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| NEWS 12 | Jul 02 | FOREGE no longer contains STANDARDS file segment |
| NEWS 13 | Jul 22 | USAN to be reloaded July 28, 2002; saved answer sets no longer valid |
| NEWS 14 | Jul 29 | Enhanced polymer searching in REGISTRY |
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| NEWS 19 | Aug 19 | Aquatic Toxicity Information Retrieval (AQUIRE) now available on STN |
| NEWS 20 | Aug 19 | IFIPAT, IFICDB, and IFIUDB have been reloaded |
| NEWS 21 | Aug 19 | The MEDLINE file segment of TOXCENTER has been reloaded |
| NEWS 22 | Aug 26 | Sequence searching in REGISTRY enhanced |
| NEWS 23 | Sep 03 | JAPIO has been reloaded and enhanced |
| NEWS 24 | Sep 16 | Experimental properties added to the REGISTRY file |
| NEWS 25 | Sep 16 | Indexing added to some pre-1967 records in CA/CAPLUS |
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FILE 'USPATFULL' ENTERED AT 10:44:01 ON 28 OCT 2002
CA INDEXING COPYRIGHT (C) 2002 AMERICAN CHEMICAL SOCIETY (ACS)

FILE COVERS 1971 TO PATENT PUBLICATION DATE: 24 Oct 2002 (20021024/PD)
FILE LAST UPDATED: 24 Oct 2002 (20021024/ED)
HIGHEST GRANTED PATENT NUMBER: US6470498
HIGHEST APPLICATION PUBLICATION NUMBER: US2002157162
CA INDEXING IS CURRENT THROUGH 24 Oct 2002 (20021024/UPCA)
ISSUE CLASS FIELDS (/INCL) CURRENT THROUGH: 24 Oct 2002 (20021024/PD)
REVISED CLASS FIELDS (/NCL) LAST RELOADED: Aug 2002
USPTO MANUAL OF CLASSIFICATIONS THESAURUS ISSUE DATE: Aug 2002

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This file contains CAS Registry Numbers for easy and accurate substance identification.

=> s intestinal polypeptide
23870 INTESTINAL
37401 POLYPEPTIDE
L1 309 INTESTINAL POLYPEPTIDE
(INTESTINAL(W) POLYPEPTIDE)

=> s l1 and sexual dysfunction?
6812 SEXUAL
14360 DYSFUNCTION?

1116 SEXUAL DYSFUNCTION?

(SEXUAL(W) DYSFUNCTION?)

L2 36 L1 AND SEXUAL DYSFUNCTION?

=> d 12 1-36 bib, ab,

L2 ANSWER 1 OF 36 USPATFULL
 AN 2002:276096 USPATFULL
 TI Treatment of female **sexual dysfunction** using phosphodiesterase inhibitors
 IN Place, Virgil A., Kawaihae, HI, United States
 Wilson, Leland F., Menlo Park, CA, United States
 Doherty, Jr., Paul C., Cupertino, CA, United States
 Hanamoto, Mark S., Belmont, CA, United States
 Spivack, Alfred P., Menlo Park, CA, United States
 Gesundheit, Neil, Los Altos, CA, United States
 Bennett, Sean R., Denver, CO, United States
 PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)
 PI US 6469016 B1 20021022
 AI US 2000-499959 20000208 (9)
 RLI Division of Ser. No. US 1998-181316, filed on 27 Oct 1998, now abandoned
 Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997,
 now patented, Pat. No. US 5877216 Continuation-in-part of Ser. No. US
 1997-959057, filed on 28 Oct 1997, now abandoned
 DT Utility
 FS GRANTED
 EXNAM Primary Examiner: Criares, Theodore J.
 LREP Reed & Associates, Reed, Diane E.
 CLMN Number of Claims: 64
 ECL Exemplary Claim: 1
 DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
 LN.CNT 1559
 AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar area or urethra of the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and others. The formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.

L2 ANSWER 2 OF 36 USPATFULL
 AN 2002:276093 USPATFULL
 TI Pyrazolopyrimidinones for the treatment of impotence
 IN Ellis, Peter, Sandwich, UNITED KINGDOM
 Terrett, Nicholas Kenneth, Sandwich, UNITED KINGDOM
 PA Pfizer Inc, New York, NY, United States (U.S. corporation)
 PI US 6469012 B1 20021022
 WO 9428902 19941222
 AI US 1996-549792 19960304 (8)
 WO 1994-EP1580 19940513
 19960304 PCT 371 date
 PRAI GB 1993-11920 19930609
 DT Utility
 FS GRANTED
 EXNAM Primary Examiner: Webman, Edward J.

LREP Richardson, Peter C., Benson, Gregg C., Jones, James T.
 CLMN Number of Claims: 26
 ECL Exemplary Claim: 1
 DRWN 0 Drawing Figure(s); 0 Drawing Page(s)
 LN.CNT 1185
 AB The use of a compound of formula (I) ##STR1##

wherein R.sup.1 is H; C.sub.1-C.sub.3 alkyl; C.sub.1-C.sub.3 perfluoroalkyl; or C.sub.3-C.sub.5 cycloalkyl; R.sup.2 is H; optionally substituted C.sub.1-C.sub.6 alkyl; C.sub.1-C.sub.3 perfluoroalkyl; or C.sub.3-C.sub.6 cycloalkyl; R.sup.3 is optionally substituted C.sub.1-C.sub.6 alkyl; C.sub.1-C.sub.6 perfluoroalkyl; C.sub.3-C.sub.5 cycloalkyl; C.sub.3-C.sub.6 alkenyl; or C.sub.3-C.sub.6 alkynyl; R.sup.4 is optionally substituted C.sub.1-C.sub.4 alkyl, C.sub.2-C.sub.4 alkenyl, C.sub.2-C.sub.4 alkanoyl, (hydroxy)C.sub.2-C.sub.4 alkyl or (C.sub.2-C.sub.3 alkoxy)C.sub.1-C.sub.2 alkyl; CONR.sup.5R.sup.6; CO.sub.2R.sup.7; halo; NR.sup.5R.sup.6; NHSO.sub.2NR.sup.5R.sup.6; NHSO.sub.2R.sup.8; SO.sub.2NR.sup.9R.sup.10; or phenyl, pyridyl, pyrimidinyl, imidazolyl, oxazolyl, thiazolyl, thienyl or triazolyl any of which is optionally substituted with methyl; R.sup.5 and R.sup.6 are each independently H or C.sub.1-C.sub.4 alkyl, or together with the nitrogen atom to which they are attached form an optionally substituted pyrrolidinyl, piperidino, morpholino, 4-N(R.sup.11)-piperazinyl or imidazolyl group; R.sup.7 is H or C.sub.1-C.sub.4 alkyl; R.sup.8 is optionally substituted C.sub.1-C.sub.3 alkyl; R.sup.9 and R.sup.10 together with the nitrogen atom to which they are attached form an optionally substituted pyrrolidinyl, piperidino, morpholino or 4-N(R.sup.12)-piperazinyl group; R.sup.11 is H; optionally substituted C.sub.1-C.sub.3 alkyl; (hydroxy)C.sub.2-C.sub.3 alkyl; or C.sub.1-C.sub.4 alkanoyl; R.sup.12 is H; optionally substituted C.sub.1-C.sub.6 alkyl; CONR.sup.13R.sup.14; CSNR.sup.13R.sup.14; or C(NH)NR.sup.13R.sup.14; and R¹³? and R.sup.14 are each independently H; C.sub.1-C.sub.4 alkyl; or substituted C.sub.2-C.sub.4 alkyl; or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in a male animal, including man; a pharmaceutical composition for said treatment; and a method of said treatment of said male animal with said pharmaceutical composition or with said either entity.

L2 ANSWER 3 OF 36 USPATFULL
 AN 2002:273397 USPATFULL
 TI Transcobalamin receptor binding conjugates useful for treating abnormal cellular proliferation
 IN Collins, Douglas A., Rochester, MN, UNITED STATES
 Hogenkamp, Henricus P.C., Roseville, MN, UNITED STATES
 PI US 2002151525 A1 20021017
 AI US 2001-27593 A1 20011025 (10)
 PRAI US 2000-243082P 20001025 (60)
 US 2000-243112P 20001025 (60)
 DT Utility
 FS APPLICATION
 LREP KING & SPALDING, 191 PEACHTREE STREET, N.E., ATLANTA, GA, 30303-1763
 CLMN Number of Claims: 28
 ECL Exemplary Claim: 1
 DRWN 6 Drawing Page(s)
 LN.CNT 4143
 AB An agent, composition and method for the treatment, prophylaxis and/or diagnosis of proliferative disorders, which is highly and efficiently

absorbed at the site of abnormal cellular proliferation is disclosed.

L2 ANSWER 4 OF 36 USPATFULL
 AN 2002:262363 USPATFULL
 TI Carboline derivatives as cGMP phosphodiesterase inhibitors
 IN Bombrun, Agnes, Monnetier Mornex, FRANCE
 Gellibert, Fran.cedilla.oise, Paris Cedex, FRANCE
 PA ICOS Corporation, Bothell, WA, United States (U.S. corporation)
 PI US 6462047 B1 20021008
 WO 2000015639 20000323
 AI US 2001-744859 20010516 (9)
 WO 1998-EP6050 19980916
 20010516 PCT 371 date

DT Utility
 FS GRANTED
 EXNAM Primary Examiner: Huang, Evelyn Mei
 LREP Marshall, Gerstein & Borun.
 CLMN Number of Claims: 22
 ECL Exemplary Claim: 1
 DRWN 0 Drawing Figure(s); 0 Drawing Page(s)
 LN.CNT 1490

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Compounds of general structural formula (I) wherein A represents a 5- or 6-membered heteroaryl group containing at least one heteroatom selected from the group consisting of oxygen, nitrogen, and sulfur, and use of the compounds, and salts and solvates thereof, as therapeutic agents, are disclosed. ##STR1##

L2 ANSWER 5 OF 36 USPATFULL
 AN 2002:246766 USPATFULL
 TI Method of treating sexual disturbances
 IN Meglasson, Martin Durham, Kalamazoo, MI, United States
 McCall, Robert B., Kalamazoo, MI, United States
 PA Pharmacia & Upjohn Company, Kalamazoo, MI, United States (U.S. corporation)
 PI US 6455564 B1 20020924
 AI US 1999-465668 19991217 (9)
 PRAI US 1999-120543P 19990217 (60)
 US 1999-115922P 19990114 (60)
 US 1999-115051P 19990108 (60)
 US 1999-114840P 19990106 (60)

DT Utility
 FS GRANTED
 EXNAM Primary Examiner: Travers, Russell; Assistant Examiner: Hui, San-ming
 LREP Stein, Bruce
 CLMN Number of Claims: 14
 ECL Exemplary Claim: 1
 DRWN 0 Drawing Figure(s); 0 Drawing Page(s)
 LN.CNT 1059

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention is a method of treating sexual disturbances in humans and inducing mating in non-human mammals using the compounds of formula (A) ##STR1##

in a dosage range where the sexually therapeutic amount is from about 0.2 thru 8 mg/person/dose and where the sexually mating amount is from about 0.003 thru 0.2 mg/kg/dose.

L2 ANSWER 6 OF 36 USPATFULL
 AN 2002:199138 USPATFULL

TI Method of treating sexual disturbances
 IN McCall, Robert B., Kalamazoo, MI, UNITED STATES
 Meglasson, Martin Durham, Kalamazoo, MI, UNITED STATES
 PI US 2002107247 A1 20020808
 AI US 2002-78611 A1 20020219 (10)
 RLI Division of Ser. No. US 1999-465668, filed on 17 Dec 1999, PENDING
 PRAI US 1999-120543P 19990217 (60)
 US 1999-115922P 19990114 (60)
 US 1999-115051P 19990108 (60)
 US 1999-114840P 19990106 (60)
 DT Utility
 FS APPLICATION
 LREP Austin W. Zhang, Pharmacia & Upjohn Company, Global Intellectual
 Property, 301 Henrietta Street, Kalamazoo, MI, 49001
 CLMN Number of Claims: 10
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 1885

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention is a method of treating sexual disturbances in
 humans and inducing mating in non-human mammals using the compounds of
 formula (A) ##STR1##

in a dosage range where the sexually therapeutic amount is from about
 0.2 thru 8 mg/person/dose and where the sexually mating amount is from
 about 0.003 thru 0.2 mg/kg/dose.

L2 ANSWER 7 OF 36 USPATFULL
 AN 2002:186082 USPATFULL
 TI Treatment of female **sexual dysfunction** with
 vasoactive agents, particularly vasoactive **intestinal**
polypeptide and agonists thereof
 IN Wilson, Leland F., Menlo Park, CA, UNITED STATES
 Place, Virgil A., Kawaihae, HI, UNITED STATES
 PI US 2002099003 A1 20020725
 AI US 2001-929818 A1 20010813 (9)
 RLI Continuation-in-part of Ser. No. US 2000-498522, filed on 4 Feb 2000,
 ABANDONED Division of Ser. No. US 1998-181316, filed on 27 Oct 1998,
 ABANDONED Continuation-in-part of Ser. No. US 1997-959064, filed on 28
 Oct 1997, PATENTED Continuation-in-part of Ser. No. US 1997-959057,
 filed on 28 Oct 1997, ABANDONED
 DT Utility
 FS APPLICATION
 LREP REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO PARK, CA, 94025
 CLMN Number of Claims: 40
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 1901

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods for treating female **sexual dysfunction** are
 provided. A pharmaceutical composition containing a vasoactive agent
 selected from vasoactive **intestinal polypeptide**
 (VIP) and VIP agonists is administered to the vagina and/or vulvar
 region of the individual undergoing treatment. The formulations are also
 useful for improving vaginal muscle tone and tissue health, enhancing
 vaginal lubrication, and minimizing excess collagen deposition.
 Pharmaceutical formulations and kits are also provided.

L2 ANSWER 8 OF 36 USPATFULL
 AN 2002:181667 USPATFULL

TI Microdose therapy
 IN Heaton, Jeremy P. W., Gananoque, CANADA
 Adams, Michael A., Kingston, CANADA
 Banting, James D., Kingston, CANADA
 PA Queens University at Kingston, CANADA (non-U.S. corporation)
 PI US 6423683 B1 20020723
 AI US 2000-613637 20000711 (9)
 RLI Continuation of Ser. No. US 1999-469649, filed on 22 Dec 1999, now
 patented, Pat. No. US 6165975 Continuation of Ser. No. WO 1998-CA603,
 filed on 22 Jun 1998
 PRAI US 1998-86750P 19980527 (60)
 US 1997-50491P 19970623 (60)
 DT Utility
 FS GRANTED
 EXNAM Primary Examiner: Henley, III, Raymond
 LREP Steeg, Carol Miernicki, Scribner, Stephen J., Tyrrell, Kathleen A.
 CLMN Number of Claims: 36
 ECL Exemplary Claim: 1
 DRWN 12 Drawing Figure(s); 8 Drawing Page(s)
 LN.CNT 1302

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods for treating vascular conditions associated with localized
 imbalance in vascular tone, which are hypothesized to be largely due to
 elevated endothelin (ET) are provided. The methods involve
 administration of nitric oxide (NO), agents which are able to provide
 NO, such as NO donors, agents which activate guanyl cyclase, such as
 YC-1, or agents which prolong the actions of endogenous NO or cyclic
 guanosine monophosphate (cGMP; a 2nd messenger molecule), such as
 phosphodiesterase (PDE) inhibitors. According to the invention, such
 agents are administered in minimal doses or microdoses by any route
 known in the art, so as to provide dosages which are about one half to
 about one twentieth (1/2 to {fraction (1/20)}) of those known to induce
 vasodilation in "normal" circulations. The low doses of these agents
 effectively alleviate vascular conditions associated with a reduction in
 NO production or an attenuation of NO effect, by restoring balance in
 vascular tone while exerting almost no systemic effect in normal
 vasculature.

L2 ANSWER 9 OF 36 USPATFULL

AN 2002:172331 USPATFULL

TI Microdose therapy

IN Heaton, Jeremy P.W., Gananoque, CANADA
 Adams, Michael A., Kingston, CANADA
 Banting, James D., Kingston, CANADA

PA Queen's University at Kingston, Kingston, CANADA (non-U.S. corporation)

PI US 2002091088 A1 20020711

AI US 2002-95654 A1 20020308 (10)

RLI Continuation of Ser. No. US 2000-613637, filed on 11 Jul 2000, PENDING
 Division of Ser. No. US 1999-469649, filed on 22 Dec 1999, GRANTED, Pat.
 No. US 6165975 Continuation of Ser. No. WO 1998-CA603, filed on 22 Jun
 1998, UNKNOWN

PRAI US 1998-86750P 19980527 (60)

US 1997-50491P 19970623 (60)

DT Utility

FS APPLICATION

LREP TOWNSEND AND TOWNSEND AND CREW, LLP, TWO EMBARCADERO CENTER, EIGHTH
 FLOOR, SAN FRANCISCO, CA, 94111-3834

CLMN Number of Claims: 24

ECL Exemplary Claim: 1

DRWN 8 Drawing Page(s)

LN.CNT 1241

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods for treating vascular conditions associated with localized imbalance in vascular tone, which are hypothesized to be largely due to elevated endothelin (ET) are provided. The methods involve administration of nitric oxide (NO), agents which are able to provide NO, such as NO donors, agents which activate guanyl cyclase, such as YC-1, or agents which prolong the actions of endogenous NO or cyclic guanosine monophosphate (cGMP; a 2nd messenger molecule), such as phosphodiesterase (PDE) inhibitors. According to the invention, such agents are administered in minimal doses or microdoses by any route known in the art, so as to provide dosages which are about one half to about one twentieth ($1/2$ to $\{fraction (1/20)\}$) of those known to induce vasodilation in "normal" circulations. The low doses of these agents effectively alleviate vascular conditions associated with a reduction in NO production or an attenuation of NO effect, by restoring balance in vascular tone while exerting almost no systemic effect in normal vasculature.

L2 ANSWER 10 OF 36 USPATFULL

AN 2002:152192 USPATFULL

TI Antagonism of endothelin actions

IN Banting, James D., Kingston, CANADA
 Heaton, Jeremy P. W., Gananaque, CANADA
 Adams, Michael A., Kingston, CANADA

PA Queen's University at Kingston, CANADA (non-U.S. corporation)

PI US 6410007 B1 20020625

AI US 1998-152874 19980914 (9)

RLI Continuation of Ser. No. WO 1997-CA169, filed on 13 Mar 1997
 Continuation-in-part of Ser. No. US 1996-615659, filed on 13 Mar 1996,
 now patented, Pat. No. US 5688499

DT Utility

FS GRANTED

EXNAM Primary Examiner: Wang, Andrew; Assistant Examiner: Lacourciere, Karen A.

CLMN Number of Claims: 11

ECL Exemplary Claim: 1

DRWN 5 Drawing Figure(s); 4 Drawing Page(s)

LN.CNT 1001

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The mechanism of hypertension following acute NO synthase blockage is via endothelin-mediated vasoconstriction. Thus, NO appears to inhibit endothelin activity by blocking its expression and not as a chronic direct acting vasodilator. Administration of an endothelin antagonist to a patient in a 'normal' physiological state may result in specific regional vasodilation. This treatment finds utility in the treatment of erectile dysfunction.

L2 ANSWER 11 OF 36 USPATFULL

AN 2002:126808 USPATFULL

TI Use of CLC3 chloride channel blockers to modulate vascular tone

IN Lamb, Fred S., Solon, IA, UNITED STATES
 Schutte, Brian C., Iowa City, IA, UNITED STATES
 Yang, Baoli, Cedar Rapids, IA, UNITED STATES

PI US 2002065325 A1 20020530

AI US 2001-930105 A1 20010815 (9)

RLI Continuation-in-part of Ser. No. US 2000-512926, filed on 25 Feb 2000,
 PENDING

PRAI US 1999-121727P 19990226 (60)

DT Utility

FS APPLICATION
 LREP SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A., P.O. BOX 2938, MINNEAPOLIS, MN, 55402

CLMN Number of Claims: 43

ECL Exemplary Claim: 1

DRWN 18 Drawing Page(s)

LN.CNT 2662

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention provides methods for the modulation of vascular tone in a patient having compromised vascular tissue, which methods comprise the administration of a chloride channel blocking agent or a pharmaceutically acceptable salt thereof.

L2 ANSWER 12 OF 36 USPATFULL

AN 2002:22468 USPATFULL

TI As-needed administration of an androgenic agent to enhance female sexual desire and responsiveness

IN Wilson, Leland F., Menlo Park, CA, UNITED STATES

Tam, Peter Y., Redwood City, CA, UNITED STATES

PI US 2002013304 A1 20020131

AI US 2001-919472 A1 20010727 (9)

RLI Continuation-in-part of Ser. No. US 2000-539484, filed on 30 Mar 2000, GRANTED, Pat. No. US 6306841 Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, ABANDONED Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, GRANTED, Pat. No. US 5877216 Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997, ABANDONED

DT Utility

FS APPLICATION

LREP REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO PARK, CA, 94025

CLMN Number of Claims: 62

ECL Exemplary Claim: 1

DRWN No Drawings

LN.CNT 1970

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method is provided for enhancing a female individual's sexual desire and responsiveness. The method involves administration of a pharmaceutical formulation containing an effective amount of an androgenic agent, wherein administration is on an as-needed basis rather than involving chronic pharmacotherapy. Local delivery may be accomplished via administration to the vagina, vulvar area or urethra of the individual, although oral administration is preferred for those androgenic agents that are orally active. Formulations and kits for carrying out the method are provided as well.

L2 ANSWER 13 OF 36 USPATFULL

AN 2002:8498 USPATFULL

TI Transmucosal administration of phosphodiesterase inhibitors for the treatment of erectile dysfunction

IN Doherty, Paul C., JR., Cupertino, CA, UNITED STATES

Place, Virgil A., Kawaihae, HI, UNITED STATES

Smith, William L., Mahwah, NJ, UNITED STATES

PI US 2002004498 A1 20020110

AI US 2001-938417 A1 20010823 (9)

RLI Continuation of Ser. No. US 1999-467094, filed on 10 Dec 1999, PENDING Continuation-in-part of Ser. No. US 1998-181070, filed on 27 Oct 1998, GRANTED, Pat. No. US 6037346 Continuation-in-part of Ser. No. US 1997-958816, filed on 28 Oct 1997, ABANDONED

DT Utility

FS APPLICATION

09/393704

LREP REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO PARK, CA, 94025
CLMN Number of Claims: 58
ECL Exemplary Claim: 1
DRWN No Drawings
LN.CNT 1200

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method is provided for treating erectile dysfunction in a mammalian male individual. The method involves the transmucosal administration of a phosphodiesterase inhibitor or a pharmaceutically acceptable salt, ester, amide or derivative thereof, within the context of an effective dosing regimen. Preferred modes of administration include transbuccal, sublingual and transrectal routes. Pharmaceutical formulations and kits are provided as well.

L2 ANSWER 14 OF 36 USPATFULL

AN 2001:229703 USPATFULL

TI Co-administration of a prostaglandin and an androgenic agent in the treatment of female **sexual dysfunction**

IN Place, Virgil A., Kawaihae, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Paul C., JR., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States

PI US 2001051656 A1 20011213

AI US 2001-905458 A1 20010713 (9)

RLI Continuation of Ser. No. US 2000-539484, filed on 30 Mar 2000, PENDING
Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, ABANDONED
Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, GRANTED, Pat. No. US 5877216 Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997, ABANDONED

DT Utility

FS APPLICATION

LREP REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO PARK, CA, 94025

CLMN Number of Claims: 59

ECL Exemplary Claim: 1

DRWN 1 Drawing Page(s)

LN.CNT 1333

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar area or urethra of the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists smooth muscle relaxants leukotriene inhibitors, and other. The formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.

L2 ANSWER 15 OF 36 USPATFULL

AN 2001:212445 USPATFULL

TI 6-heterocyclyl pyrazolo [3,4-d]pyrimidin-4-one cGMP-PDE inhibitors for the treatment of erectile dysfunction

IN Campbell, Simon Fraser, Sandwich, Great Britain
Mackenzie, Alexander Roderick, Sandwich, Great Britain
Wood, Anthony, Sandwich, Great Britain

09/393704

PI US 2001044441 A1 20011122
AI US 2001-880141 A1 20010613 (9)
RLI Division of Ser. No. US 1997-836670, filed on 22 May 1997, PENDING A 371
of International Ser. No. WO 1995-EP4066, filed on 16 Oct 1995, UNKNOWN
PRAI GB 1994-23910 19941126
DT Utility
FS APPLICATION
LREP Gregg C. Benson, Pfizer Inc., Patent Department, MS 4159, Eastern Point
Road, Groton, CT, 06340
CLMN Number of Claims: 7
ECL Exemplary Claim: 1
DRWN No Drawings
LN.CNT 397

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB 6-heterocyclcyl pyrazolo [3,4-d]pyrimidin-4-one compounds which are
selective inhibitors of cGMP PDE are useful in the treatment of erectile
dysfunction (impotence) in male animals, including man.

L2 ANSWER 16 OF 36 USPATFULL

AN 2001:185276 USPATFULL

TI Treatment of female **sexual dysfunction**

IN Place, Virgil A., Kawaihae, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Jr., Paul C., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States

PA ASIVI, LLC, Mountain View, CA, United States (U.S. corporation)

PI US 6306841 B1 20011023

AI US 2000-539484 20000330 (9)

RLI Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, now
abandoned Continuation-in-part of Ser. No. US 1997-959064, filed on 28
Oct 1997, now patented, Pat. No. US 5877216 Continuation of Ser. No. US
1997-959057, filed on 28 Oct 1997, now abandoned

DT Utility

FS GRANTED

EXNAM Primary Examiner: Criares, Theodore J.

LREP Reed, Dianne E. Reed & Associates

CLMN Number of Claims: 31

ECL Exemplary Claim: 1

DRWN 1 Drawing Figure(s); 1 Drawing Page(s)

LN.CNT 1196

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods and formulations for treating female **sexual
dysfunction** are provided. A pharmaceutical composition
formulated so as to contain a selected vasoactive agent is administered
to the vagina, vulvar area or urethra of the individual undergoing
treatment. Suitable vasoactive agents are vasodilators, including
naturally occurring prostaglandins, synthetic prostaglandin derivatives,
endothelial-derived relaxation factors, vasoactive **intestinal
polypeptide** agonists, smooth muscle relaxants, leukotriene
inhibitors, and others. The formulations are also useful for preventing
the occurrence of yeast infections, improving vaginal muscle tone and
tissue health, enhancing vaginal lubrication, and minimizing excess
collagen deposition. A clitoral drug delivery device is also provided.

L2 ANSWER 17 OF 36 USPATFULL

AN 2001:173589 USPATFULL

TI 4-aminoquinazoline derivative cGMP-PDE inhibitors for the treatment of

erectile dysfunction

IN Campbell, Simon Fraser, Sandwich, United Kingdom
Mackenzie, Alexander Roderick, Sandwich, United Kingdom
Wood, Anthony, Sandwich, United Kingdom

PA Pfizer Inc., New York, NY, United States (U.S. corporation)

PI US 6300335 B1 20011009
WO 9616644 19960606

AI US 1997-836670 19970522 (8)
WO 1995-EP4066 19951016
19970522 PCT 371 date
19970522 PCT 102(e) date

PRAI GB 1994-23910 19941126

DT Utility

FS GRANTED

EXNAM Primary Examiner: Cook, Rebecca

LREP Richardson, Peter C., Benson, Gregg C., Jones, James T.

CLMN Number of Claims: 3

ECL Exemplary Claim: 1

DRWN No Drawings

LN.CNT 496

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB 4-aminoquinazoline derivatives which are selective inhibitors of cGMP
PDE are useful in the treatment of erectile dysfunction (impotence) in
male animals, including man.

L2 ANSWER 18 OF 36 USPATFULL

AN 2001:163217 USPATFULL

TI Treatment of female **sexual dysfunction**

IN Place, Virgil A., Kawaihee, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Jr., Paul C., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States

PA Asivi, LLC, Mountain View, CA, United States (U.S. corporation)

PI US 6294550 B1 20010925

AI US 2000-501098 20000209 (9)

RLI Division of Ser. No. US 1998-181316, filed on 27 Oct 1998
Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997,
now patented, Pat. No. US 5877216 Continuation-in-part of Ser. No. US
1997-959057, filed on 28 Oct 1997, now abandoned

DT Utility

FS GRANTED

EXNAM Primary Examiner: Criares, Theodore J.

LREP Reed, Dianne E. Reed & Associates

CLMN Number of Claims: 29

ECL Exemplary Claim: 1

DRWN 2 Drawing Figure(s); 1 Drawing Page(s)

LN.CNT 1195

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition
formulated so as to contain a selected vasoactive agent is administered
to the vagina, vulvar area or urethra of the individual undergoing
treatment. Suitable vasoactive agents are vasodilators, including
naturally occurring prostaglandins, synthetic prostaglandin derivatives,
endothelial-derived relaxation factors, vasoactive **intestinal polypeptide**
agonists, smooth muscle relaxants, leukotriene
inhibitors, and others. The formulations are also useful for preventing

the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.

L2 ANSWER 19 OF 36 USPATFULL

AN 2001:52073 USPATFULL

TI Use of nicorandil in treatment of **sexual dysfunction**
or for enhancement of sexual function in mammals including humans

IN Saxena, Ajit, Uttar Pradesh, IN, United States

Bakhle, Dhananjay Sadashiv, Mumbai, IN, United States

PA Lupin Laboratories Limited, Mumbai, India (non-U.S. corporation)

PI US 6214849 B1 20010410

AI US 1999-326052 19990604 (9)

PRAI IN 1999-32599 19990429

DT Utility

FS Granted

EXNAM Primary Examiner: Webman, Edward J.

LREP Ladas & Parry

CLMN Number of Claims: 22

ECL Exemplary Claim: 1

DRWN 4 Drawing Figure(s); 2 Drawing Page(s)

LN.CNT 1169

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention discloses the use of nicorandil in treatment of male impotency and female **sexual dysfunction**. Nitric ester of N-(2-hydroxyethyl) nicotinamide or nicorandil, as it is better known is known as a drug for treatment of circulatory diseases. It is a pyridine derivative. Several clinical tests performed on male patients suffering from impotency including severe penile erectile dysfunction or female patients suffering from female sexual arousal dysfunction consistently showed excellent results. There was not a single instance of any of side effects or other symptoms of toxicity or deaths due to myocardial infarctions as was the case with other drugs including pyrazolopyrimidones compounds.

L2 ANSWER 20 OF 36 USPATFULL

AN 2001:36442 USPATFULL

TI Method of administration of sildenafil to produce instantaneous response for the treatment of erectile dysfunction

IN Hussain, Anwar A., 886 McMeekin Pl., Lexington, KY, United States 40502

Dittert, Lewis W., 4999 Hartland Pkwy., Lexington, KY, United States 40515

PI US 6200591 B1 20010313

AI US 1998-208439 19981210 (9)

PRAI US 1998-90740P 19980625 (60)

DT Utility

FS Granted

EXNAM Primary Examiner: Azpuru, Carlos A.

LREP Burns, Doane, Swecker & Mathis, L.L.P.

CLMN Number of Claims: 12

ECL Exemplary Claim: 1

DRWN 1 Drawing Figure(s); 1 Drawing Page(s)

LN.CNT 641

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB This invention provides a method of rapidly and reliably delivering sildenafil, or derivatives thereof, alone or in combination with other compounds, to the systemic circulation by administration via the nasal route so as to produce virtually instantaneous onset of beneficial effects in the treatment of erectile dysfunction. The present invention further provides pharmaceutical compositions comprising sildenafil, or

derivatives thereof, and/or pharmaceutically acceptable salts thereof in a variety of unique pharmaceutical dosage forms, with and without apomorphine.

L2 ANSWER 21 OF 36 USPATFULL
 AN 2000:174603 USPATFULL
 TI Microdose therapy
 IN Adams, Michael A., Kingston, Canada
 Heaton, Jeremy P. W., Gananoque, Canada
 Banting, James D., Kingston, Canada
 PA Queen's University at Kingston, Kingston, Canada (non-U.S. corporation)
 PI US 6165975 20001226
 AI US 1999-469649 19991222 (9)
 RLI Continuation of Ser. No. WO 1998-CA603, filed on 22 Jun 1998
 PRAI US 1997-50491P 19970623 (60)
 US 1998-86750P 19980527 (60)
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Henley, III, Raymond
 LREP Steeg, Carol Miernicki, Janssen, Jerry F., Wilhelm, Thomas D.
 CLMN Number of Claims: 48
 ECL Exemplary Claim: 1
 DRWN 12 Drawing Figure(s); 8 Drawing Page(s)
 LN.CNT 1391

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method of treatment, in an organism, of a vascular condition, comprising administration of at least one agent at a level which enhances NO and which does not appreciably alter normal systemic vascular tone in said organism. At least one agent is an NO donor selected from the group consisting of glyceryl trinitrate, isosorbide 5-mononitrate, isosorbide dinitrate, pentaerythritol tetranitrate, erythrityl tetranitrate, sodium nitroprusside, 3-morpholinolinosydnonimine molsidomine, S-nitroso-N-acetylpenicillamine, S-nitrosoglutathione, and N-hydroxy-L-arginine.

L2 ANSWER 22 OF 36 USPATFULL
 AN 2000:164509 USPATFULL
 TI Local administration of type III phosphodiesterase inhibitors for the treatment of erectile dysfunction
 IN Doherty, Jr., Paul C., Cupertino, CA, United States
 Place, Virgil A., Kawaihae, HI, United States
 Smith, William L., Mahwah, NJ, United States
 PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)
 PI US 6156753 20001205
 AI US 1999-437682 19991110 (9)
 RLI Continuation-in-part of Ser. No. US 1998-181070, filed on 27 Oct 1998, now patented, Pat. No. US 6037346 which is a continuation-in-part of Ser. No. US 1997-958816, filed on 28 Oct 1997, now abandoned
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Reamer, James H.
 LREP Reed, Dianne E. Reed & Associates
 CLMN Number of Claims: 67
 ECL Exemplary Claim: 1
 DRWN 4 Drawing Figure(s); 4 Drawing Page(s)
 LN.CNT 1246

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method is provided for treating erectile dysfunction, e.g., vasculogenic erectile dysfunction such as vasculogenic impotence. The method involves the administration of a Type III phosphodiesterase

inhibitor or a pharmaceutically acceptable salt, ester, amide or derivative thereof, wherein administration is transurethral, topical or transdermal. A preferred mode of administration is transurethral. Pharmaceutical formulations and kits are provided as well.

L2 ANSWER 23 OF 36 USPATFULL
 AN 2000:150177 USPATFULL
 TI Chemical compounds
 IN Daugan, Alain Claude-Marie, Marly le Roi Cedex, France
 LaBaudiniere, Richard Frederick, Collegeville, PA, United States
 PA ICOS Corporation, Bothell, WA, United States (U.S. corporation)
 PI US 6143757 20001107
 AI US 1998-154619 19980916 (9)
 RLI Continuation-in-part of Ser. No. WO 1996-EP3023, filed on 11 Jul 1996
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Cintins, Marianne M.; Assistant Examiner:
 Delacroix-Muirhead, C
 LREP Marshall, O' Toole, Gerstein, Murray & Borun
 CLMN Number of Claims: 13
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 1803
 CAS INDEXING IS AVAILABLE FOR THIS PATENT.
 AB Compounds of the general structural formula ##STR1## and use of the
 compounds and salts and solvates thereof, as therapeutic agents.

L2 ANSWER 24 OF 36 USPATFULL
 AN 2000:150166 USPATFULL
 TI Tetracyclic cyclic GMP-specific phosphodiesterase inhibitors, process of
 preparation and use
 IN Daugan, Alain Claude-Marie, Marly le Roi Cedex, France
 Gellibert, Francoise, Marly le Roi Cedex, France
 PA ICOS Corporation, Bothell, WA, United States (U.S. corporation)
 PI US 6143746 20001107
 AI US 1998-154051 19980916 (9)
 RLI Continuation-in-part of Ser. No. WO 1995-EP183, filed on 19 Jan 1995,
 now patented, Pat. No. WO 5859006 which is a continuation-in-part of
 Ser. No. WO 1996-EP3025, filed on 11 Jul 1996, now patented, Pat. No. WO
 5981527 which is a continuation-in-part of Ser. No. WO 1996-EP3024,
 filed on 11 Jul 1996
 PRAI GB 1994-1090 19940121
 GB 1995-14465 19950714
 GB 1995-14474 19950714
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Cintins, Marianne M.; Assistant Examiner:
 Delacroix-Muirheid, C.
 LREP Marshall, O'Toole, Gerstein, Murray & Borun
 CLMN Number of Claims: 13
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 3174
 CAS INDEXING IS AVAILABLE FOR THIS PATENT.
 AB A compound of formula (I) and salts and solvates thereof, in which:
 R.sup.0 represents hydrogen, halogen, or C.sub.1-6 alkyl; R.sup.1
 represents hydrogen, C.sub.1-6 alkyl, C.sub.2-6 alkenyl, C.sub.2-6
 alkynyl, haloC.sub.1-6 alkyl, C.sub.3-8 cycloalkyl, C.sub.3-8
 cycloalkylC.sub.1-3 alkyl, arylC.sub.1-3 alkyl, or heteroarylC.sub.1-3
 alkyl; R.sup.2 represents an optionally substituted monocyclic aromatic

ring selected from benzene, thiophene, furan, and pyridine, or an optionally substituted bicyclic ring (a) attached to the rest of the molecule via one of the benzene ring carbon atoms, and wherein the fused ring (A) is a 5- or 6-membered ring which may be saturated or partially or fully unsaturated, and comprises carbon atoms and optionally one or two heteroatoms selected from oxygen, sulphur, and nitrogen; and R.sup.3 represents hydrogen or C.sub.1-3 alkyl, or R.sup.1 and R.sup.3 together represent a 3- or 4-membered alkyl or alkenyl chain. A compound of formula (I) is a potent and selective inhibitor of cyclic guanosine 3',5'-monophosphate specific phosphodiesterase (cGMP specific PDE) having a utility in a variety of therapeutic areas where such inhibition is beneficial, including the treatment of cardiovascular disorders and erectile dysfunction.

L2 ANSWER 25 OF 36 USPATFULL
 AN 2000:146375 USPATFULL
 TI Use of cGMP-phosphodiesterase inhibitors in methods and compositions to treat impotence
 IN Daugan, Alain Claude-Marie, Les Ulis, France
 PA ICOS Corporation, Bothell, WA, United States (U.S. corporation)
 PI US 6140329 20001031
 WO 9703675 19970206
 AI US 1998-981989 19980310 (8)
 WO 1996-EP3024 19960711
 19980310 PCT 371 date
 19980310 PCT 102(e) date
 PRAI GB 1995-14464 19950714
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Moezie, Minna
 LREP Marshall, O'Toole, Gerstein, Murray & Borun
 CLMN Number of Claims: 21
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 839
 CAS INDEXING IS AVAILABLE FOR THIS PATENT.
 AB The use of (6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione, (3S 6R,12aR)-2,3,6,7,12,12a-hexahydro-2,3-dimethyl-6-(3,4-methylenedioxyphenyl)-pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione, and physiologically acceptable salts and solvates thereof, in methods and compositions for the treatment of impotence.

L2 ANSWER 26 OF 36 USPATFULL
 AN 2000:131835 USPATFULL
 TI Local administration of Type IV phosphodiesterase inhibitors for the treatment of erectile dysfunction
 IN Doherty, Jr., Paul C., Cupertino, CA, United States
 Place, Virgil A., Kawaihae, HI, United States
 Smith, William L., Montclair, NJ, United States
 PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)
 PI US 6127363 20001003
 AI US 1999-437999 19991110 (9)
 RLI Continuation-in-part of Ser. No. US 1998-181070, filed on 27 Oct 1998, now patented, Pat. No. US 6037346 which is a continuation-in-part of Ser. No. US 1997-958816, filed on 28 Oct 1997, now abandoned
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Reamer, James H.
 LREP Reed, Dianne E. Reed & Associates

09/393704

CLMN Number of Claims: 106
ECL Exemplary Claim: 1
DRWN 7 Drawing Figure(s); 4 Drawing Page(s)
LN.CNT 1455

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method is provided for treating erectile dysfunction, e.g.,
vasculogenic erectile dysfunction such as vasculogenic impotence. The
method involves the administration of a Type IV phosphodiesterase
inhibitor or a pharmaceutically acceptable salt, ester, amide or
derivative thereof, wherein administration is local, i.e.,
transurethral, intracavernosal, topical or transdermal. A preferred mode
of administration is transurethral. Pharmaceutical formulations and kits
are provided as well.

L2 ANSWER 27 OF 36 USPATFULL

AN 2000:102303 USPATFULL

TI Bicyclic heterocyclic compounds for the treatment of impotence

IN Campbell, Simon Fraser, Sandwich, United Kingdom

PA Pfizer Inc., New York, NY, United States (U.S. corporation)

PI US 6100270 20000808

WO 9616657 19960606

AI US 1997-836671 19970522 (8)

WO 1995-EP4065 19951016

19970522 PCT 371 date

19970522 PCT 102(e) date

PRAI GB 1994-23911 19941126

DT Utility

FS Granted

EXNAM Primary Examiner: Cook, Rebecca

LREP Richardson, Peter C., Benson, Gregg C., Jones, James T.

CLMN Number of Claims: 3

ECL Exemplary Claim: 1

DRWN No Drawings

LN.CNT 465

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method of treating male erectile dysfunction comprising administering
to a male human a pyrimidine compound of formula I.

L2 ANSWER 28 OF 36 USPATFULL

AN 2000:47212 USPATFULL

TI Stimulating sexual response in females

IN Hadley, Mac E., 1921 Calle Campana de Plata, Tucson, AZ, United States
85745

PI US 6051555 20000418

AI US 1998-179225 19981027 (9)

RLI Continuation of Ser. No. US 1996-699571, filed on 19 Aug 1996, now
abandoned which is a continuation of Ser. No. US 1994-264921, filed on
24 Jun 1994, now patented, Pat. No. US 5576290 which is a continuation
of Ser. No. US 1993-43159, filed on 5 Apr 1993, now abandoned

DT Utility

FS Granted

EXNAM Primary Examiner: Russel, Jeffrey E.

LREP Yahwak & Associates

CLMN Number of Claims: 8

ECL Exemplary Claim: 1

DRWN No Drawings

LN.CNT 657

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention is directed to a series of peptides which may be
used for stimulating sexual response in females.

L2 ANSWER 29 OF 36 USPATFULL
 AN 2000:37808 USPATFULL
 TI Carboline derivatives
 IN Bombrun, Agnes, Paris, France
 PA Icos Corporation, Bothell, WA, United States (U.S. corporation)
 PI US 6043252 20000328
 AI US 1998-154052 19980916 (9)
 RLI Continuation-in-part of Ser. No. WO 1997-EP2277, filed on 5 May 1997
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Jones, Dwayne C.; Assistant Examiner:
 Delacroix-Muirheid, C.
 LREP Marshall, O'Toole, Gerstein, Murray & Borun
 CLMN Number of Claims: 14
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 4016

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Carboline derivatives of formula (I) ##STR1## are potent and selective inhibitors of cyclic guanosine 3',5'-monophosphate specific phosphodiesterase (cGMP-specific PDE) and have utility in a variety of therapeutic areas where such inhibition is thought to be beneficial, including the treatment of cardiovascular disorders and erectile dysfunction.

L2 ANSWER 30 OF 36 USPATFULL
 AN 2000:31420 USPATFULL
 TI Local administration of phosphodiesterase inhibitors for the treatment of erectile dysfunction
 IN Doherty, Jr., Paul C., Cupertino, CA, United States
 Place, Virgil A., Kawaihae, HI, United States
 Smith, William L., Mahwah, NJ, United States
 PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)
 PI US 6037346 20000314
 AI US 1998-181070 19981027 (9)
 RLI Continuation-in-part of Ser. No. US 1997-958816, filed on 28 Oct 1997, now abandoned
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Reamer, James H.
 LREP Reed, Dianne E. Reed & Associates
 CLMN Number of Claims: 94
 ECL Exemplary Claim: 1,23
 DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
 LN.CNT 1331

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method is provided for treating erectile dysfunction in a mammalian male individual. The method involves the local administration of a phosphodiesterase inhibitor or a pharmaceutically acceptable salt, ester, amide or derivative thereof within the context of an effective dosing regimen. A preferred mode of administration is transurethral. Pharmaceutical formulations and kits are provided as well.

L2 ANSWER 31 OF 36 USPATFULL
 AN 1999:81821 USPATFULL
 TI Transurethral administration of androgenic agents for the treatment of erectile dysfunction
 IN Place, Virgil A., Kawaihae, HI, United States
 PA VIVUS, Incorporated, Mountain View, CA, United States (U.S. corporation)

PI US 5925629 19990720
 AI US 1997-959243 19971028 (8)
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Jarvis, William R. A.
 LREP Reed, Dianne E.Bozicevic & Reed LLP
 CLMN Number of Claims: 26
 ECL Exemplary Claim: 1
 DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
 LN.CNT 786

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method is provided for treating erectile dysfunction in an individual. The method involves the administration of an androgenic steroid within the context of an effective dosing regimen. The preferred mode of administration is transurethral; however, the selected inhibitor may also be delivered via intracavernosal injection or using alternative routes. Pharmaceutical formulations and kits are provided as well.

L2 ANSWER 32 OF 36 USPATFULL

AN 1999:27675 USPATFULL

TI Treatment of female **sexual dysfunction**

IN Place, Virgil A., Kawaihae, HI, United States
 Wilson, Leland F., Menlo Park, CA, United States
 Doherty, Jr., Paul C., Cupertino, CA, United States
 Hanamoto, Mark S., Belmont, CA, United States
 Spivack, Alfred P., Menlo Park, CA, United States
 Gesundheit, Neil, Los Altos, CA, United States
 Bennett, Sean R., Denver, CO, United States

PA VIVUS, Incorporated, Mountain View, CA, United States (U.S. corporation)

PI US 5877216 19990302
 AI US 1997-959064 19971028 (8)
 DT Utility
 FS Granted

EXNAM Primary Examiner: Criares, Theodore J.
 LREP Reed, Dianne E.Bozicevic & Reed LLP
 CLMN Number of Claims: 25
 ECL Exemplary Claim: 1
 DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
 LN.CNT 953

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasodilating agent is administered to the vagina or vulvar area of the individual undergoing treatment. Suitable vasodilating agents include naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters and inclusion complexes of any of the foregoing, and mixtures thereof. The novel formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.

L2 ANSWER 33 OF 36 USPATFULL

AN 97:109873 USPATFULL

TI Methods of treating impotency with ciliary neurotrophic factor

IN Russell, Deborah A., Thousand Oaks, CA, United States

PA Amgen Inc., Thousand Oaks, CA, United States (U.S. corporation)

PI US 5691313 19971125
 AI US 1996-704479 19960826 (8)
 RLI Continuation of Ser. No. US 1994-298442, filed on 29 Aug 1994, now abandoned which is a continuation-in-part of Ser. No. US 1991-735538, filed on 23 Jul 1991, now abandoned
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Allen, Marianne P.
 LREP Levy, Ron K., Odre, Steven M.
 CLMN Number of Claims: 5
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 393
 CAS INDEXING IS AVAILABLE FOR THIS PATENT.
 AB The present invention provides methods for treating impotency with the use of a therapeutically effective amount of ciliary neurotrophic factor (CNTF). Pharmaceutical compositions containing CNTF in a pharmaceutically acceptable carrier are also provided.

L2 ANSWER 34 OF 36 USPATFULL
 AN 97:106792 USPATFULL
 TI Antagonism of endothelin actions
 IN Banting, James D., Kingston, Canada
 Heaton, Jeremy P.W., Kingston, Canada
 Adams, Michael A., Kingston, Canada
 PA Queen's University at Kingston, Kingston, Canada (non-U.S. corporation)
 PI US 5688499 19971118
 AI US 1996-615659 19960313 (8)
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Elliott, George G.; Assistant Examiner: Wang, Andrew
 LREP Hicks, Richard J.
 CLMN Number of Claims: 10
 ECL Exemplary Claim: 1
 DRWN 5 Drawing Figure(s); 4 Drawing Page(s)
 LN.CNT 804
 CAS INDEXING IS AVAILABLE FOR THIS PATENT.
 AB The mechanism of hypertension following acute NO synthase blockade is via endothelin mediated vasoconstriction. Thus, NO appears to inhibit endothelin activity by blocking its expression and not as a chronic direct acting vasodilator. Administration of an endothelin antagonist to a patient in a 'normal' physiological state may result in specific regional vasodilation. This treatment finds utility in the treatment of erectile dysfunction.

L2 ANSWER 35 OF 36 USPATFULL
 AN 96:106463 USPATFULL
 TI Compositions and methods for the diagnosis and treatment of psychogenic erectile dysfunction
 IN Hadley, Mac E., Tucson, AZ, United States
 PA Competitive Technologies, Inc., Westport, CT, United States (U.S. corporation)
 PI US 5576290 19961119
 AI US 1994-264921 19940624 (8)
 RLI Continuation of Ser. No. US 1993-43159, filed on 5 Apr 1993, now abandoned
 DT Utility
 FS Granted
 EXNAM Primary Examiner: Russel, Jeffrey E.
 LREP Yahwak & Associates

09/393704

CLMN Number of Claims: 17
ECL Exemplary Claim: 1
DRWN No Drawings
LN.CNT 693

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention is directed to a group of linear and cyclic peptides having the structures: ##STR1## These peptides, when systemically administered to animals will bring about a sexual response and are thus useful for the diagnosis and treatment of psychogenic **sexual dysfunction** in the male.

L2 ANSWER 36 OF 36 USPATFULL

AN 95:71388 USPATFULL

TI Treatments for male **sexual dysfunction**

IN Snyder, Solomon H., Baltimore, MD, United States
Burnett, Arthur L., Baltimore, MD, United States
Lowenstein, Charles J., Tacoma Park, MD, United States
Bredt, David S., Baltimore, MD, United States
Chang, Thomas S. K., Baltimore, MD, United States

PA The Johns Hopkins University, Baltimore, MD, United States (U.S. corporation)

PI US 5439938 19950808

AI US 1993-43821 19930407 (8)

DT Utility

FS Granted

EXNAM Primary Examiner: Henley, III, Raymond

LREP Banner, Birch, McKie & Beckett

CLMN Number of Claims: 33

ECL Exemplary Claim: 1

DRWN 6 Drawing Figure(s); 1 Drawing Page(s)

LN.CNT 532

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods and devices are taught for regulating penile erection and urethral function. Inhibitors of nitric oxide synthase and precursors of nitric oxide are applied to relax or contract the muscles of the corpus cavernosum and the urethra.

=> s 12 and agonist

15808 AGONIST

L3 18 L2 AND AGONIST

=> d 13 1-18

L3 ANSWER 1 OF 18 USPATFULL

AN 2002:276096 USPATFULL

TI Treatment of female **sexual dysfunction** using phosphodiesterase inhibitors

IN Place, Virgil A., Kawaihae, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Jr., Paul C., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States

PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)

PI US 6469016 B1 20021022

AI US 2000-499959 20000208 (9)

RLI Division of Ser. No. US 1998-181316, filed on 27 Oct 1998, now abandoned
Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997,

09/393704

now patented, Pat. No. US 5877216 Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997, now abandoned

DT Utility
FS GRANTED
LN.CNT 1559
INCL INCLM: 514/262.000
INCLS: 514/261.000; 514/341.000
NCL NCLM: 514/262.000
NCLS: 514/261.000; 514/341.000
IC [7]
ICM: A61K031-51
ICS: A61K031-44
EXF 514/341; 514/261; 514/262

L3 ANSWER 2 OF 18 USPATFULL
AN 2002:246766 USPATFULL
TI Method of treating sexual disturbances
IN Meglasson, Martin Durham, Kalamazoo, MI, United States
McCall, Robert B., Kalamazoo, MI, United States
PA Pharmacia & Upjohn Company, Kalamazoo, MI, United States (U.S. corporation)

PI US 6455564 B1 20020924
AI US 1999-465668 19991217 (9)
PRAI US 1999-120543P 19990217 (60)
US 1999-115922P 19990114 (60)
US 1999-115051P 19990108 (60)
US 1999-114840P 19990106 (60)

DT Utility
FS GRANTED
LN.CNT 1059
INCL INCLM: 514/387.000
NCL NCLM: 514/387.000
IC [7]
ICM: A61K031-415
EXF 514/387

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 3 OF 18 USPATFULL
AN 2002:199138 USPATFULL
TI Method of treating sexual disturbances
IN McCall, Robert B., Kalamazoo, MI, UNITED STATES
Meglasson, Martin Durham, Kalamazoo, MI, UNITED STATES
PI US 2002107247 A1 20020808
AI US 2002-78611 A1 20020219 (10)
RLI Division of Ser. No. US 1999-465668, filed on 17 Dec 1999, PENDING
PRAI US 1999-120543P 19990217 (60)
US 1999-115922P 19990114 (60)
US 1999-115051P 19990108 (60)
US 1999-114840P 19990106 (60)

DT Utility
FS APPLICATION
LN.CNT 1885
INCL INCLM: 514/232.800
INCLS: 514/252.160; 514/267.000; 514/253.030; 514/296.000
NCL NCLM: 514/232.800
NCLS: 514/252.160; 514/267.000; 514/253.030; 514/296.000
IC [7]
ICM: A61K031-5377
ICS: A61K031-519; A61K031-496; A61K031-4745

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 4 OF 18 USPATFULL
AN 2002:186082 USPATFULL
TI Treatment of female **sexual dysfunction** with
vasoactive agents, particularly vasoactive **intestinal**
polypeptide and agonists thereof
IN Wilson, Leland F., Menlo Park, CA, UNITED STATES
Place, Virgil A., Kawaihae, HI, UNITED STATES
PI US 2002099003 A1 20020725
AI US 2001-929818 A1 20010813 (9)
RLI Continuation-in-part of Ser. No. US 2000-498522, filed on 4 Feb 2000,
ABANDONED Division of Ser. No. US 1998-181316, filed on 27 Oct 1998,
ABANDONED Continuation-in-part of Ser. No. US 1997-959064, filed on 28
Oct 1997, PATENTED Continuation-in-part of Ser. No. US 1997-959057,
filed on 28 Oct 1997, ABANDONED
DT Utility
FS APPLICATION
LN.CNT 1901
INCL INCLM: 514/002.000
INCLS: 514/171.000; 514/182.000
NCL NCLM: 514/002.000
NCLS: 514/171.000; 514/182.000
IC [7]
ICM: A61K038-17
ICS: A61K031-56
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 5 OF 18 USPATFULL
AN 2002:181667 USPATFULL
TI Microdose therapy
IN Heaton, Jeremy P. W., Gananoque, CANADA
Adams, Michael A., Kingston, CANADA
Banting, James D., Kingston, CANADA
PA Queens University at Kingston, CANADA (non-U.S. corporation)
PI US 6423683 B1 20020723
AI US 2000-613637 20000711 (9)
RLI Continuation of Ser. No. US 1999-469649, filed on 22 Dec 1999, now
patented, Pat. No. US 6165975 Continuation of Ser. No. WO 1998-CA603,
filed on 22 Jun 1998
PRAI US 1998-86750P 19980527 (60)
US 1997-50491P 19970623 (60)
DT Utility
FS GRANTED
LN.CNT 1302
INCL INCLM: 514/002.000
INCLS: 514/192.000; 514/231.200; 514/470.000; 514/565.000; 514/668.000
NCL NCLM: 514/002.000
NCLS: 514/192.000; 514/231.200; 514/470.000; 514/565.000; 514/668.000
IC [7]
ICM: A61K038-00
ICS: A61K031-43; A61K031-535; A61K031-34; A61K031-195; A61K031-13
EXF 514/2; 514/192; 514/231.2; 514/470; 514/565; 514/668
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 6 OF 18 USPATFULL
AN 2002:172331 USPATFULL
TI Microdose therapy
IN Heaton, Jeremy P.W., Gananoque, CANADA
Adams, Michael A., Kingston, CANADA
Banting, James D., Kingston, CANADA

09/393704

PA Queen's University at Kingston, Kingston, CANADA (non-U.S. corporation)
PI US 2002091088 A1 20020711
AI US 2002-95654 A1 20020308 (10)
RLI Continuation of Ser. No. US 2000-613637, filed on 11 Jul 2000, PENDING
Division of Ser. No. US 1999-469649, filed on 22 Dec 1999, GRANTED, Pat.
No. US 6165975 Continuation of Ser. No. WO 1998-CA603, filed on 22 Jun
1998, UNKNOWN
PRAI US 1998-86750P 19980527 (60)
US 1997-50491P 19970623 (60)
DT Utility
FS APPLICATION
LN.CNT 1241
INCL INCLM: 514/018.000
INCLS: 424/608.000; 514/509.000; 514/236.200
NCL NCLM: 514/018.000
NCLS: 424/608.000; 514/509.000; 514/236.200
IC [7]
ICM: A61K038-06
ICS: A61K031-5377; A61K031-21
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 7 OF 18 USPATFULL
AN 2002:152192 USPATFULL
TI Antagonism of endothelin actions
IN Banting, James D., Kingston, CANADA
Heaton, Jeremy P. W., Gananaque, CANADA
Adams, Michael A., Kingston, CANADA
PA Queen's University at Kingston, CANADA (non-U.S. corporation)
PI US 6410007 B1 20020625
AI US 1998-152874 19980914 (9)
RLI Continuation of Ser. No. WO 1997-CA169, filed on 13 Mar 1997
Continuation-in-part of Ser. No. US 1996-615659, filed on 13 Mar 1996,
now patented, Pat. No. US 5688499
DT Utility
FS GRANTED
LN.CNT 1001
INCL INCLM: 424/078.350
INCLS: 424/092.000; 514/002.000; 514/012.000
NCL NCLM: 424/078.350
NCLS: 424/009.200; 514/002.000; 514/012.000
IC [7]
ICM: A61K049-00
ICS: A61K038-00; A61N031-17; G01N031-00
EXF 514/4; 514/2; 514/44; 514/12; 536/24.5; 536/44; 424/9.2; 424/78.35
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 8 OF 18 USPATFULL
AN 2002:126808 USPATFULL
TI Use of CLC3 chloride channel blockers to modulate vascular tone
IN Lamb, Fred S., Solon, IA, UNITED STATES
Schutte, Brian C., Iowa City, IA, UNITED STATES
Yang, Baoli, Cedar Rapids, IA, UNITED STATES
PI US 2002065325 A1 20020530
AI US 2001-930105 A1 20010815 (9)
RLI Continuation-in-part of Ser. No. US 2000-512926, filed on 25 Feb 2000,
PENDING
PRAI US 1999-121727P 19990226 (60)
DT Utility
FS APPLICATION
LN.CNT 2662

09/393704

INCL INCLM: 514/651.000
INCLS: 514/212.010; 514/317.000; 514/428.000
NCL NCLM: 514/651.000
NCLS: 514/212.010; 514/317.000; 514/428.000
IC [7]
ICM: A61K031-137
ICS: A61K031-55; A61K031-445; A61K031-40
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 9 OF 18 USPATFULL
AN 2002:22468 USPATFULL
TI As-needed administration of an androgenic agent to enhance female sexual
desire and responsiveness
IN Wilson, Leland F., Menlo Park, CA, UNITED STATES
Tam, Peter Y., Redwood City, CA, UNITED STATES
PI US 2002013304 A1 20020131
AI US 2001-919472 A1 20010727 (9)
RLI Continuation-in-part of Ser. No. US 2000-539484, filed on 30 Mar 2000,
GRANTED, Pat. No. US 6306841 Continuation of Ser. No. US 1998-181316,
filed on 27 Oct 1998, ABANDONED Continuation-in-part of Ser. No. US
1997-959064, filed on 28 Oct 1997, GRANTED, Pat. No. US 5877216
Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997,
ABANDONED
DT Utility
FS APPLICATION
LN.CNT 1970
INCL INCLM: 514/177.000
NCL NCLM: 514/177.000
IC [7]
ICM: A61K031-56
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 10 OF 18 USPATFULL
AN 2001:229703 USPATFULL
TI Co-administration of a prostaglandin and an androgenic agent in the
treatment of female **sexual dysfunction**
IN Place, Virgil A., Kawaihae, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Paul C., JR., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States
PI US 2001051656 A1 20011213
AI US 2001-905458 A1 20010713 (9)
RLI Continuation of Ser. No. US 2000-539484, filed on 30 Mar 2000, PENDING
Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, ABANDONED
Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997,
GRANTED, Pat. No. US 5877216 Continuation-in-part of Ser. No. US
1997-959057, filed on 28 Oct 1997, ABANDONED
DT Utility
FS APPLICATION
LN.CNT 1333
INCL INCLM: 514/530.000
INCLS: 514/573.000; 514/288.000
NCL NCLM: 514/530.000
NCLS: 514/573.000; 514/288.000
IC [7]
ICM: A61K031-5575
ICS: A61K031-48

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 11 OF 18 USPATFULL
AN 2001:185276 USPATFULL
TI Treatment of female **sexual dysfunction**
IN Place, Virgil A., Kawaihae, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Jr., Paul C., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States
PA ASIVI, LLC, Mountain View, CA, United States (U.S. corporation)
PI US 6306841 B1 20011023
AI US 2000-539484 20000330 (9)
RLI Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, now
abandoned Continuation-in-part of Ser. No. US 1997-959064, filed on 28
Oct 1997, now patented, Pat. No. US 5877216 Continuation of Ser. No. US
1997-959057, filed on 28 Oct 1997, now abandoned
DT Utility
FS GRANTED
LN.CNT 1196
INCL INCLM: 514/149.000
INCLS: 514/150.000; 514/236.500; 514/236.800; 514/530.000; 514/573.000
NCL NCLM: 514/149.000
NCLS: 514/150.000; 514/236.500; 514/236.800; 514/530.000; 514/573.000
IC [7]
ICM: A61K031-655
ICS: A61K031-535; A61K031-557; A61K031-19
EXF 514/149; 514/150; 514/236.5; 514/236.8; 514/573
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 12 OF 18 USPATFULL
AN 2001:163217 USPATFULL
TI Treatment of female **sexual dysfunction**
IN Place, Virgil A., Kawaihee, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Jr., Paul C., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States
PA Asivi, LLC, Mountain View, CA, United States (U.S. corporation)
PI US 6294550 B1 20010925
AI US 2000-501098 20000209 (9)
RLI Division of Ser. No. US 1998-181316, filed on 27 Oct 1998
Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997,
now patented, Pat. No. US 5877216 Continuation-in-part of Ser. No. US
1997-959057, filed on 28 Oct 1997, now abandoned
DT Utility
FS GRANTED
LN.CNT 1195
INCL INCLM: 514/302.000
NCL NCLM: 514/302.000
IC [7]
ICM: A61K031-44
EXF 514/302
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 13 OF 18 USPATFULL

09/393704

AN 2001:52073 USPATFULL
TI Use of nicorandil in treatment of **sexual dysfunction**
or for enhancement of sexual function in mammals including humans
IN Saxena, Ajit, Uttar Pradesh, IN, United States
Bakhle, Dhananjay Sadashiv, Mumbai, IN, United States
PA Lupin Laboratories Limited, Mumbai, India (non-U.S. corporation)
PI US 6214849 B1 20010410
AI US 1999-326052 19990604 (9)
PRAI IN 1999-32599 19990429
DT Utility
FS Granted
LN.CNT 1169
INCL INCLM: 514/355.000
INCLS: 514/906.000
NCL NCLM: 514/355.000
NCLS: 514/906.000
IC [7]
ICM: A61P015-10
ICS: A61K031-4406
EXF 514/355; 514/906; 514/356
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 14 OF 18 USPATFULL
AN 2000:174603 USPATFULL
TI Microdose therapy
IN Adams, Michael A., Kingston, Canada
Heaton, Jeremy P. W., Gananoque, Canada
Banting, James D., Kingston, Canada
PA Queen's University at Kingston, Kingston, Canada (non-U.S. corporation)
PI US 6165975 20001226
AI US 1999-469649 19991222 (9)
RLI Continuation of Ser. No. WO 1998-CA603, filed on 22 Jun 1998
PRAI US 1997-50491P 19970623 (60)
US 1998-86750P 19980527 (60)
DT Utility
FS Granted
LN.CNT 1391
INCL INCLM: 514/002.000
INCLS: 514/192.000; 514/231.200; 514/470.000; 514/565.000; 514/668.000
NCL NCLM: 514/002.000
NCLS: 514/192.000; 514/231.200; 514/470.000; 514/565.000; 514/668.000
IC [7]
ICM: A61K038-00
ICS: A61K031-43; A61K031-535; A61K031-34; A61K031-195; A61K031-13
EXF 514/2; 514/192; 514/231.2; 514/470; 514/565; 514/668
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 15 OF 18 USPATFULL
AN 2000:47212 USPATFULL
TI Stimulating sexual response in females
IN Hadley, Mac E., 1921 Calle Campana de Plata, Tucson, AZ, United States
85745
PI US 6051555 20000418
AI US 1998-179225 19981027 (9)
RLI Continuation of Ser. No. US 1996-699571, filed on 19 Aug 1996, now
abandoned which is a continuation of Ser. No. US 1994-264921, filed on
24 Jun 1994, now patented, Pat. No. US 5576290 which is a continuation
of Ser. No. US 1993-43159, filed on 5 Apr 1993, now abandoned
DT Utility
FS Granted

09/393704

LN.CNT 657

INCL INCLM: 514/011.000

INCLS: 514/016.000

NCL NCLM: 514/011.000

NCLS: 514/016.000

IC [7]

ICM: A61K038-08

ICS: A61K038-12

EXF 814/9; 814/11; 814/15; 814/16; 930/DIG.572; 930/DIG.582; 530/312;

530/317; 530/321; 530/328; 530/329

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 16 OF 18 USPATFULL

AN 1999:27675 USPATFULL

TI Treatment of female **sexual dysfunction**

IN Place, Virgil A., Kawaihae, HI, United States

Wilson, Leland F., Menlo Park, CA, United States

Doherty, Jr., Paul C., Cupertino, CA, United States

Hanamoto, Mark S., Belmont, CA, United States

Spivack, Alfred P., Menlo Park, CA, United States

Gesundheit, Neil, Los Altos, CA, United States

Bennett, Sean R., Denver, CO, United States

PA VIVUS, Incorporated, Mountain View, CA, United States (U.S. corporation)

PI US 5877216 19990302

AI US 1997-959064 19971028 (8)

DT Utility

FS Granted

LN.CNT 953

INCL INCLM: 514/573.000

NCL NCLM: 514/573.000

IC [6]

ICM: A61K031-557

ICS: A61K031-19

EXF 514/530; 514/573

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 17 OF 18 USPATFULL

AN 97:106792 USPATFULL

TI Antagonism of endothelin actions

IN Banting, James D., Kingston, Canada

Heaton, Jeremy P.W., Kingston, Canada

Adams, Michael A., Kingston, Canada

PA Queen's University at Kingston, Kingston, Canada (non-U.S. corporation)

PI US 5688499 19971118

AI US 1996-615659 19960313 (8)

DT Utility

FS Granted

LN.CNT 804

INCL INCLM: 424/078.350

INCLS: 424/009.200; 514/002.000; 514/012.000

NCL NCLM: 424/078.350

NCLS: 424/009.200; 514/002.000; 514/012.000

IC [6]

ICM: A61K049-00

ICS: A61K038-00; G01N031-00; A61N031-17

EXF 514/12; 514/44; 514/2; 536/24.5; 536/44; 424/9.2; 424/78.35

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

L3 ANSWER 18 OF 18 USPATFULL

AN 96:106463 USPATFULL

09/393704

TI Compositions and methods for the diagnosis and treatment of psychogenic
erectile dysfunction
IN Hadley, Mac E., Tucson, AZ, United States
PA Competitive Technologies, Inc., Westport, CT, United States (U.S.
corporation)
PI US 5576290 19961119
AI US 1994-264921 19940624 (8)
RLI Continuation of Ser. No. US 1993-43159, filed on 5 Apr 1993, now
abandoned
DT Utility
FS Granted
LN.CNT 693
INCL INCLM: 514/011.000
INCLS: 424/009.100; 436/811.000; 514/016.000; 530/312.000; 930/DIG.572;
930/DIG.582
NCL NCLM: 514/011.000
NCLS: 424/009.100; 436/811.000; 514/016.000; 530/312.000; 930/DIG.572;
930/DIG.582
IC [6]
ICM: A61K038-08
ICS: A61K038-12; A61K049-00; C07K014-685
EXF 514/9; 514/11; 514/15; 514/16; 930/DIG.572; 930/DIG.582; 530/312;
530/317; 530/321; 530/328; 530/329; 424/9.1; 436/811
CAS INDEXING IS AVAILABLE FOR THIS PATENT.

=> s 13 and pd<2000
2601897 PD<2000
(PD<200000000)

L4 3 L3 AND PD<2000

=> d 14 1-3 bib, ab, kwic

L4 ANSWER 1 OF 3 USPATFULL
AN 1999:27675 USPATFULL
TI Treatment of female **sexual dysfunction**
IN Place, Virgil A., Kawaihae, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Jr., Paul C., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States
PA VIVUS, Incorporated, Mountain View, CA, United States (U.S. corporation)
PI US 5877216 19990302 <--
AI US 1997-959064 19971028 (8)
DT Utility
FS Granted
EXNAM Primary Examiner: Criares, Theodore J.
LREP Reed, Dianne E.Bozicevic & Reed LLP
CLMN Number of Claims: 25
ECL Exemplary Claim: 1
DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
LN.CNT 953
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
AB Methods and formulations for treating female **sexual
dysfunction** are provided. A pharmaceutical composition
formulated so as to contain a selected vasodilating agent is
administered to the vagina or vulvar area of the individual undergoing
treatment. Suitable vasodilating agents include naturally occurring

prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters and inclusion complexes of any of the foregoing, and mixtures thereof. The novel formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.

TI Treatment of female **sexual dysfunction**

PI US 5877216 19990302 <--

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasodilating agent is administered to the vagina or. . . area of the individual undergoing treatment. Suitable vasodilating agents include naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters and inclusion complexes of any of the foregoing, and mixtures. . .

SUMM This invention relates generally to methods and pharmaceutical formulations for treating female **sexual dysfunction**, and more particularly relates to vaginal and/or vulvar administration of a vasodilating agent, such as a prostaglandin, in such treatment.. . .

SUMM . . . vaginal surface lubrication as a result of plasma transudation that saturates the fluid reabsorptive capacity of the vaginal epithelium. Vasoactive **intestinal polypeptide** ("VIP") release may induce the physiological changes of sexual arousal and excitement, and may be the major neurotransmitter which participates. . .

SUMM . . . characteristic genital and extragenital responses occur. Estrogens magnify the sexual responses; however, sexual responses may also occur in estrogen-deficient individuals. **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. . . For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York: Brunner-Mazel, 1983), and Kolodny et al.,. . .

SUMM Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health. . .

SUMM . . . of menstrual periods. Accordingly, there remains a need in the art to provide safer and more effective treatments of female **sexual dysfunction**.

SUMM . . . present invention is directed to the aforementioned need in the art, and provides a new, highly effective method of treating **sexual dysfunction**. The method involves vaginal and/or vulvar administration of a pharmaceutical formulation containing one or more vasodilating agents, e.g., a prostaglandin. . .

SUMM Drug therapy for treating female **sexual dysfunction** has been described. For example, U.S. Pat. No. 4,507,323 to Stern describes the use of the anxiolytic m-chloro-.alpha.-t-butylamino-propiofenone in the treatment of **sexual dysfunction** in male and female individuals. Pharmaceutical compositions containing

the agent are described, which are presented in discrete units, e.g., cachets, . . .

SUMM Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals using the stereoisomers of octahydropyrimido[4,5-g]quinoline agents, centrally acting dopamine agonists.

SUMM . . . mentioned as being suitable for use in conjunction with the device. However, the Zaffaroni patent does not mention treatment of **sexual dysfunction**, nor is application of a drug-containing composition to the clitoris or vulvar area disclosed or suggested. U.S. Pat. No. 3,948,254. . .

SUMM . . . mention that delivery of prostaglandins is a preferred use of the invention; however, there is no disclosure concerning treatment of **sexual dysfunction** or delivery to the clitoris.

SUMM . . . disclosure concerning vaginal drug delivery, application of a drug-containing formulation to the clitoris or surrounding vulvar area, or treatment of **sexual dysfunction**.

SUMM . . . contraceptives, labor and delivery, and thus fail to disclose or suggest the use of these compounds in the treatment of **sexual dysfunction**.

SUMM There are, accordingly, a number of background references relating to treatment of female **sexual dysfunction** as well as cervical or uterine administration of prostaglandins. However, the present method for treating female **sexual dysfunction**, by way of vaginal and/or vulvar delivery of a vasodilating agent such as a prostaglandin, is completely novel and unsuggested. . .

SUMM Accordingly, it is a primary object of the invention to provide a method for treating **sexual dysfunction** in a female individual by administering a pharmaceutical formulation containing a selected vasodilating agent to the vagina and/or vulvar area. . .

SUMM In one aspect of the invention, then, a method is provided for treating **sexual dysfunction** in a female individual comprising vaginally administering a pharmaceutical formulation containing a selected vasodilating agent. The vasodilating agent is selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters and inclusion complexes of any of the foregoing, and mixtures. . .

SUMM In a related aspect of the invention, the aforementioned method of treating **sexual dysfunction** is carried out by applying the pharmaceutical composition to the vulvar area of the individual undergoing treatment, as an alternative. . .

DETD . . . meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect. For example, in treating **sexual dysfunction** in women, an "effective" amount of drug would be an amount which is at least sufficient to provide the desired. . .

DETD In a first embodiment, the invention relates to a method for treating **sexual dysfunction** in a female individual and involves vaginal administration of a pharmaceutical formulation containing a vasodilating agent selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters and inclusion complexes of any of the foregoing, and mixtures. . .

DETD In an alternative embodiment, the invention involves a method for treating **sexual dysfunction** in a female individual by administering such a pharmaceutical formulation to the vulvar area of

the individual, as an alternative. . .

DETD . . . the latter group represented by compounds such as S-nitroso-N-acetyl-D,L-penicillamine ("SNAP"), S-nitroso-N-cysteine and S-nitroso-N-glutathione ("SNO-GLU"). Still other vasodilating agents include vasoactive **intestinal polypeptide** agonists and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .

DETD . . . one or more pharmacologically active agents other than the vasodilator. For example, the formulations may contain a steroid, a steroid **agonist**, partial **agonist**, or antagonist. Steroids will generally be selected from the group consisting of progestogens, estrogens, pharmaceutically acceptable salts and esters of. . .

DETD For treatment of **sexual dysfunction**, the pharmaceutical formulation is administered either vaginally, or to the vulvar area, or both. The amount of active agent administered. . .

DETD In addition to treatment of **sexual dysfunction**, the formulations of the invention have other uses as well. They may be administered vaginally to prevent the occurrence of. . .

DETD Individuals are assessed and pre-screened to assemble an experimental group of subjects suffering from **sexual dysfunction**. The formulations prepared in Examples 1-6 are each assessed in the experimental subjects for their ability to increase uterine or. . .

CLM What is claimed is:

1. A method for treating **sexual dysfunction** in a female individual, comprising administering to the vagina and/or vulvar area of the individual a pharmaceutical formulation comprising an. . .
11. The method of claim 1, wherein the pharmaceutical formulation further includes a compound which is a steroid **agonist**, partial **agonist** or antagonist.

L4 ANSWER 2 OF 3 USPATFULL

AN 97:106792 USPATFULL

TI Antagonism of endothelin actions

IN Banting, James D., Kingston, Canada
Heaton, Jeremy P.W., Kingston, Canada
Adams, Michael A., Kingston, Canada

PA Queen's University at Kingston, Kingston, Canada (non-U.S. corporation)

PI US 5688499 19971118 <--

AI US 1996-615659 19960313 (8)

DT Utility

FS Granted

EXNAM Primary Examiner: Elliott, George G.; Assistant Examiner: Wang, Andrew

LREP Hicks, Richard J.

CLMN Number of Claims: 10

ECL Exemplary Claim: 1

DRWN 5 Drawing Figure(s); 4 Drawing Page(s)

LN.CNT 804

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The mechanism of hypertension following acute NO synthase blockade is via endothelin mediated vasoconstriction. Thus, NO appears to inhibit endothelin activity by blocking its expression and not as a chronic direct acting vasodilator. Administration of an endothelin antagonist to a patient in a 'normal' physiological state may result in specific regional vasodilation. This treatment finds utility in the treatment of erectile dysfunction.

PI US 5688499 19971118 <--

SUMM . . . much more redundancy in control of vasodilation. For example,

vasodilation can be induced by acetylcholine, bradykinin, adenosine-triphosphate (ATP), histamine, vasoactive **intestinal polypeptide** (VIP), and leukotrienes, amongst others. The actions of these endogenous modulators have been shown to be dependent on the presence. . .

SUMM . . . one type of injectable therapy. The secondary effects and indirect costs associated with erectile dysfunction would suggest that impotence and **sexual dysfunction** are medical icebergs. The consequences of **sexual dysfunction** may be seen in strains on the host relationship potentially leading to marital breakdown, violence, work related sequelae, deviant sexual. .

SUMM . . . surprisingly, a variety of other NANC systems have also been shown to play a role in erectile function including vasoactive **intestinal polypeptide** (VIP) (Gu et al, 1983 (37) & (38); Willis et al, 1983 (39)), calcitonin gene related peptide (CGRP) (Stief, 1990). . .

DETD . . . isolated perfusion of the pudendal vasculature preparation have been assessed. FIG. 3 illustrates the dose response curve to the .alpha.-adrenoceptor **agonist** methoxamine (MXA) alone. FIG. 4 illustrates the dose-response curve to endothelin alone. Table 2 represents the changes in perfusion pressure. . .

DETD TABLE 2

A comparison of the perfusion pressure responses in control and endothelin subpressor treated rats to the .alpha..sup.1 -adrenoceptor

agonist

methoxamine.

(.DELTA. Perfusion Pressure (mmHg)

[methoxamine .mu.g/ml

Control Endothelin sub-pressor

| | | |
|----------|---|------------|
| 0 | 0 | 0 |
| 0.1 | 0 | 0 |
| 0.25 | 0 | 34 .+-. 2 |
| 0.5 | 0 | 93 .+-. 30 |
| 1.0. . . | | |

L4 ANSWER 3 OF 3 USPATFULL

AN 96:106463 USPATFULL

TI Compositions and methods for the diagnosis and treatment of psychogenic erectile dysfunction

IN Hadley, Mac E., Tucson, AZ, United States

PA Competitive Technologies, Inc., Westport, CT, United States (U.S. corporation)

PI US 5576290 19961119 <--

AI US 1994-264921 19940624 (8)

RLI Continuation of Ser. No. US 1993-43159, filed on 5 Apr 1993, now abandoned

DT Utility

FS Granted

EXNAM Primary Examiner: Russel, Jeffrey E.

LREP Yahwak & Associates

CLMN Number of Claims: 17

ECL Exemplary Claim: 1

DRWN No Drawings

LN.CNT 693

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB The present invention is directed to a group of linear and cyclic peptides having the structures: ##STR1## These peptides, when

systemically administered to animals will bring about a sexual response and are thus useful for the diagnosis and treatment of psychogenic **sexual dysfunction** in the male.

PI US 5576290 19961119 <--

AB . . . administered to animals will bring about a sexual response and are thus useful for the diagnosis and treatment of psychogenic **sexual dysfunction** in the male.

SUMM . . . can be erect without placing much demand on cardiac output. Although many details remain unclear, increasing evidence indicates that vasoactive **intestinal polypeptide**, perhaps aided by alpha-adrenergic blockade, acetylcholine, and nitric oxide controls the vascular changes that occur during erection.

SUMM While there is presently no consensus treatment for **sexual dysfunction** in the male, most drug strategies are directed as though the defect were primary (at the level of the penis). . .

SUMM . . . has been discovered to prolong erections. Although its side effects are such that trazodone is not an acceptable therapy for **sexual dysfunction**, it does indicate that alternative less invasive routes of administration are possible for the treatment of such conditions.

SUMM . . . such activity. Oxytocin appears to be a central stimulant of erectile function, and there is evidence that apomorphine (a dopamine **agonist**) induces penile erection by releasing oxytocin in the central nervous system. The clinical applicability of apomorphine is, however, partially limited. . .

SUMM It is one aspect of the present invention, therefore, to describe a means of distinguishing psychogenic impotence from **sexual dysfunction** brought about by organic pathologies or vascular insufficiencies.

SUMM It is a second aspect of the present invention to provide a male with a means to overcome **sexual dysfunction** caused for psychogenic reasons.

SUMM . . . present invention to describe a series of compounds active in bringing about an enhancement of libido (either by overcoming psychogenic **sexual dysfunction** in males or by inducing sexual receptivity in females) in animals (specifically in mammals, and more specifically in, but not. . .

DETD . . . allow the physician to determine whether CNS-derived impulses from the brain to the penis are intact. If so, then the **sexual dysfunction** can be ascribed as being psychogenic in nature. Failure to respond to the peptides according to the present invention might. . .

DETD In addition to providing a safe therapy for **sexual dysfunction**, the peptides of the present invention may also be administered subcutaneously or intramuscularly by the physician to provide a rapid. . .

CLM What is claimed is:

. . . the administration of the peptide wherein an erectogenic effect resulting from the administration of said peptide is diagnostic of psychogenic **sexual dysfunction**.

=> s 13 and androsterone

359 ANDROSTERONE

L5 6 L3 AND ANDROSTERONE

=> d 15 1-6 bib, ab, kwic

L5 ANSWER 1 OF 6 USPATFULL

AN 2002:276096 USPATFULL

TI Treatment of female **sexual dysfunction** using phosphodiesterase inhibitors

IN Place, Virgil A., Kawaihae, HI, United States
 Wilson, Leland F., Menlo Park, CA, United States
 Doherty, Jr., Paul C., Cupertino, CA, United States
 Hanamoto, Mark S., Belmont, CA, United States
 Spivack, Alfred P., Menlo Park, CA, United States
 Gesundheit, Neil, Los Altos, CA, United States
 Bennett, Sean R., Denver, CO, United States

PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)

PI US 6469016 B1 20021022

AI US 2000-499959 20000208 (9)

RLI Division of Ser. No. US 1998-181316, filed on 27 Oct 1998, now abandoned
 Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, now patented, Pat. No. US 5877216 Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997, now abandoned

DT Utility

FS GRANTED

EXNAM Primary Examiner: Criares, Theodore J.

LREP Reed & Associates, Reed, Diane E.

CLMN Number of Claims: 64

ECL Exemplary Claim: 1

DRWN 1 Drawing Figure(s); 1 Drawing Page(s)

LN.CNT 1559

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar area or urethra of the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and others. The formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.

TI Treatment of female **sexual dysfunction** using phosphodiesterase inhibitors

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar. . . the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and others. The formulations are also useful for preventing the occurrence of yeast infections, . . .

SUMM This invention relates generally to methods and pharmaceutical formulations for treating female **sexual dysfunction**, and more particularly relates to vaginal, vulvar and/or urethral administration of a vasoactive agent, such as a prostaglandin, in such.

SUMM . . . vaginal surface lubrication as a result of plasma transudation that saturates the fluid reabsorptive capacity of the vaginal epithelium. Vasoactive **intestinal polypeptide** ("VIP") release may induce the physiological changes of sexual arousal and excitement, and may be the major neurotransmitter that participates.

- SUMM . . . characteristic genital and extragenital responses occur. Estrogens magnify the sexual responses; however, sexual responses may also occur in estrogen-deficient individuals. **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York: Brunner-Mazel, 1983), and Kolodny et al., . . .
- SUMM Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health of. . .
- SUMM . . . of menstrual periods. Accordingly, there remains a need in the art to provide safer and more ways of treating female **sexual dysfunction**.
- SUMM . . . present invention is directed to the aforementioned need in the art, and provides a new, highly effective method of treating **sexual dysfunction** in women. The method involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, e.g., a. . .
- SUMM Drug therapy for treating female **sexual dysfunction** has been described. For example, U.S. Pat. No. 4,507,323 to Stern describes the use of the anxiolytic m-chloro-.alpha.-t-butylamino-propiofenone in the treatment of **sexual dysfunction** in both male and female individuals. Pharmaceutical compositions containing the agent are described, which are presented in discrete units, e.g., . . .
- SUMM Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals using the stereoisomers of octahydropyrimido[4,5-g]quinolines, centrally acting dopamine agonists.
- SUMM . . . are mentioned as being suitable for use in conjunction with the device. However, the patent does not mention treatment of **sexual dysfunction**, nor is application of a drug-containing composition to the clitoris, vulvar area or urethra disclosed or suggested. U.S. Pat. No. . . .
- SUMM . . . mention that delivery of prostaglandins is a preferred use of the invention; however, there is no disclosure concerning treatment of **sexual dysfunction** or delivery to the vulvar area or urethra.
- SUMM . . . drug delivery, urethral drug administration, application of a drug-containing formulation to the clitoris or surrounding vulvar area, or treatment of **sexual dysfunction**.
- SUMM . . . patents focus on the use of prostaglandins in contraceptives, labor and delivery, and do not pertain to treatment of female **sexual dysfunction**.
- SUMM Several references are also of interest herein insofar as they pertain to urethral drug administration to treat **sexual dysfunction** in men, e.g., vasculogenic impotence or the like. See, for example, U.S. Pat. Nos. 5,242,391, 5,474,535, 5,686,093 and 5,773,020 to. . .
- SUMM There are, accordingly, a number of background references relating to treatment of female **sexual dysfunction**, cervical or uterine administration of prostaglandins, and urethral drug administration in men. However, the present method for treating female **sexual dysfunction**, by way of vaginal, vulvar and/or

urethral delivery of a vasoactive agent such as a prostaglandin, is completely novel and. . .

SUMM Accordingly, it is a primary object of the invention to provide a method for treating **sexual dysfunction** in a female individual by administering a pharmaceutical formulation containing a selected vasoactive agent to the vagina, vulvar area or. . .

SUMM In one aspect of the invention, then, a method is provided for treating **sexual dysfunction** in a female individual comprising administering to the vagina, vulvar area or urethra a pharmaceutical formulation containing a selected vasoactive. . . vasodilator, with preferred vasodilators selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives and inclusion complexes thereof, and combinations of any. . .

DETD . . . meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect. For example, in treating **sexual dysfunction** in women, an "effective" amount of drug would be an amount that is at least sufficient to provide the desired. . .

DETD In a first embodiment, the invention relates to a method for treating **sexual dysfunction** in a female individual and involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, preferably. . . vasodilator. Preferred vasodilators are selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives, prodrugs, and inclusion complexes thereof, and combinations of. . .

DETD . . . (spermine NONOate or "SPER/NO") and sodium (Z)-1-(N,N-diethylamino)-diazen-1-ium-1,2-diolate (diethylamine NONOate or "DEA/NO") and derivatives thereof). Still other vasoactive agents include vasoactive **intestinal polypeptide** agonists and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .

DETD . . . more pharmacologically active agents other than the vasoactive agent. For example, the formulations may contain a steroid or a steroid **agonist**, partial **agonist**, or antagonist.

DETD . . . in the formulation. Suitable androgenic agents include, but are not limited to: the naturally occurring androgens and derivatives thereof, including **androsterone**, **androsterone** acetate, **androsterone** propionate, **androsterone** benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, ethylestrenol, oxandrolone, nandrolone phenpropionate, nandrolone decahoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate,. . .

DETD For treatment of **sexual dysfunction**, the pharmaceutical formulation is administered either vaginally, to the vulvar area, and/or to the urethra The amount of active agent. . .

DETD In addition to treatment of **sexual dysfunction**, the formulations of the invention have other uses as well. They may be administered vaginally to prevent the occurrence of. . .

DETD Individuals are assessed and pre-screened to assemble an experimental group of subjects suffering from **sexual dysfunction**.

The compositions prepared in Examples 1-6, formulated with prostaglandin E.sub.1, each assessed in the experimental subjects for their ability to. . .

CLM What is claimed is:

1. A method for treating **sexual dysfunction** in a female individual, comprising administering to the vagina and/or vulvar area of the individual a pharmaceutical formulation that comprises. . .

14. The method of claim 1, wherein the **sexual dysfunction** is an excitement stage dysfunction.

15. The method of claim 14, wherein the **sexual dysfunction** involves touch sensation impairment, loss of clitoral sensation, dyspareunia, or a combination thereof.

16. The method of claim 1, wherein the **sexual dysfunction** involves dyspareunia.

36. A method for treating **sexual dysfunction** in a female individual, comprising administering to the vagina and/or vulvar area of the individual (a) a therapeutically effective amount. . .

. . . method of claim 37, wherein the additional vasodilator is selected from the group consisting of prostaglandins, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and combinations thereof.

44. The method of claim 43, wherein the androgenic agent is selected from the group consisting of **androsterone**, **androsterone** acetate, **androsterone**, androstenediol, androstenedione, ethylestrenol, oxandrolone, nandrolone, stanozolol, dromostanolone, testosterone, dehydroepiandrosterone, 5.alpha.-dihydrotestosterone, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, and pharmaceutically acceptable esters thereof.

53. The method of claim 36, wherein the **sexual dysfunction** is an excitement stage dysfunction.

54. The method of claim 53, wherein the **sexual dysfunction** involves touch sensation impairment, loss of clitoral sensation, dyspareunia, or a combination thereof.

55. The method of claim 36, wherein the **sexual dysfunction** involves dyspareunia.

L5 ANSWER 2 OF 6 USPATFULL

AN 2002:186082 USPATFULL

TI Treatment of female **sexual dysfunction** with vasoactive agents, particularly vasoactive **intestinal polypeptide** and agonists thereof

IN Wilson, Leland F., Menlo Park, CA, UNITED STATES

Place, Virgil A., Kawaihae, HI, UNITED STATES

PI US 2002099003 A1 20020725

AI US 2001-929818 A1 20010813 (9)

RLI Continuation-in-part of Ser. No. US 2000-498522, filed on 4 Feb 2000, ABANDONED Division of Ser. No. US 1998-181316, filed on 27 Oct 1998, ABANDONED Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, PATENTED Continuation-in-part of Ser. No. US 1997-959057,

filed on 28 Oct 1997, ABANDONED

DT Utility
 FS APPLICATION
 LREP REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO PARK, CA, 94025
 CLMN Number of Claims: 40
 ECL Exemplary Claim: 1
 DRWN No Drawings
 LN.CNT 1901

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods for treating female **sexual dysfunction** are provided. A pharmaceutical composition containing a vasoactive agent selected from vasoactive **intestinal polypeptide** (VIP) and VIP agonists is administered to the vagina and/or vulvar region of the individual undergoing treatment. The formulations are also useful for improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. Pharmaceutical formulations and kits are also provided.

TI Treatment of female **sexual dysfunction** with vasoactive agents, particularly vasoactive **intestinal polypeptide** and agonists thereof

AB Methods for treating female **sexual dysfunction** are provided. A pharmaceutical composition containing a vasoactive agent selected from vasoactive **intestinal polypeptide** (VIP) and VIP agonists is administered to the vagina and/or vulvar region of the individual undergoing treatment. The formulations are.

SUMM [0002] This invention relates generally to methods and pharmaceutical formulations for treating female **sexual dysfunction**, and more particularly relates to vaginal and/or vulvar administration of a vasoactive agent, such as a prostaglandin or a vasoactive **intestinal polypeptide**, in such treatment. The invention further relates to additional methods of using the present pharmaceutical formulations, including, but not limited.

SUMM . . . vaginal surface lubrication as a result of plasma transudation that saturates the fluid reabsorptive capacity of the vaginal epithelium. Vasoactive **intestinal polypeptide** ("VIP") release may induce the physiological changes of sexual arousal and excitement, and may be the major neurotransmitter effecting neurologically.

SUMM . . . characteristic genital and extragenital responses occur. Estrogens magnify the sexual responses; however, sexual responses may also occur in estrogen-deficient individuals. **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York, N.Y.: Brunner-Mazel, 1983), and Kolodny et. . .

SUMM [0009] Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health.

SUMM . . . of menstrual periods. Accordingly, there remains a need in the art to provide safer and more ways of treating female **sexual dysfunction**.

SUMM . . . present invention is directed to the aforementioned need in the

art, and provides a new, highly effective method of treating **sexual dysfunction** in women. The method involves vaginal and/or vulvar administration of a pharmaceutical formulation containing a vasoactive agent, e.g., a prostaglandin, VIP or a VIP **agonist** or the like.

- SUMM [0012] Drug therapy for treating female **sexual dysfunction** has been described. For example, U.S. Pat. No. 4,507,323 to Stern describes the use of the anxiolytic m-chloro-.alpha.-t-butylamino-propiofenone in the treatment of **sexual dysfunction** in both male and female individuals. Pharmaceutical compositions containing the agent are described, which are presented in discrete units, e.g., . . .
- SUMM [0013] Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals using the stereoisomers of octahydropyrimido[4,5-g]quinolines, centrally acting dopamine agonists.
- SUMM . . . are mentioned as being suitable for use in conjunction with the device. However, the patent does not mention treatment of **sexual dysfunction**, nor is application of a drug-containing composition to the clitoris or vulvar region disclosed or suggested. U.S. Pat. No. 3,948,254. . .
- SUMM . . . mention that delivery of prostaglandins is a preferred use of the invention; however, there is no disclosure concerning treatment of **sexual dysfunction** or delivery to the vulvar area or urethra.
- SUMM [0021] There are, accordingly, a number of background references relating to treatment of female **sexual dysfunction**, and cervical or uterine administration of vasoactive agents. However, the present method for treating female **sexual dysfunction**, by way of vaginal and/or vulvar delivery of a vasoactive agent such as a prostaglandin or VIP or a receptor **agonist** thereof, is completely novel and unsuggested by the art.
- SUMM [0022] Accordingly, it is a primary object of the invention to provide a method for treating **sexual dysfunction** in a female individual by administering a pharmaceutical formulation containing a selected vasoactive agent to the vaginal and/or vulvar area. . .
- SUMM [0024] It is an additional object of the invention to provide such methods wherein the vasoactive agent is vasoactive **intestinal polypeptide** or an **agonist** thereof.
- SUMM [0028] In one aspect of the invention, then, a method is provided for treating **sexual dysfunction** in a female individual comprising administering to the vagina and/or vulvar area a pharmaceutical formulation containing a selected vasoactive agent. The vasoactive agent is preferably a vasodilator, with preferred vasodilators selected from the group consisting of VIP and vasoactive **intestinal polypeptide** agonists, both natural and synthetic, and combinations of any of the foregoing. Any number of drug delivery platforms may be. . .
- SUMM . . . physiological effect, i.e., in this case, enhancement of female sexual desire and responsiveness. The primary active agents herein are vasoactive **intestinal polypeptide** and agonists thereof. The terms also encompass pharmaceutically acceptable, pharmacologically active derivatives of those active agents specifically mentioned herein, including, . . .
- SUMM [0035] The pharmacologically active agents herein are vasoactive **intestinal polypeptide** and analogs thereof that serve as VIP agonists.
- SUMM . . . meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect, i.e., treatment of female **sexual dysfunction**. The amount that is "effective" will vary from

subject to subject, depending on the age and general condition of the.

- SUMM . . . prevention of the occurrence of symptoms and/or their underlying cause, and improvement or remediation of damage. Thus, for example, "treating" **sexual dysfunction**, as the term is used herein, encompasses both prevention of **sexual dysfunction** in clinically asymptomatic individuals and treatment of dysfunction in a clinically symptomatic individual.
- SUMM [0040] By "treating female **sexual dysfunction**" is meant enhancing female sexual desire and responsiveness. Applicants intend to include the treatment of disorders of female sexual desire. . . autonomic neuropathies, diabetes mellitus, and disorders of the innervation of any of the sexual organs. This term also includes substance-induced **sexual dysfunction**, including but not limited to, decreases in desire and responsiveness secondary to anti-depressants, neuroleptics, anti-hypertensives, tobacco, opiates, alcohol and any. . .
- SUMM [0048] In order to carry out the method of the invention, VIP or an **agonist** thereof is administered to the vagina and/or vulvar region of a female individual to enhance sexual desire and responsiveness; the. . .
- SUMM [0053] In a first embodiment, the invention relates to a method for treating **sexual dysfunction** in a female individual and involves vaginal and/or vulvar administration of a pharmaceutical formulation containing a vasoactive agent, preferably a vasodilator. Preferred vasodilators are selected from the group consisting of vasoactive **intestinal polypeptide**, VIP agonists, pharmaceutically acceptable salts, esters, derivatives, prodrugs, and inclusion complexes thereof, and combinations of any of the foregoing, in. . .
- SUMM [0057] Representative vasoactive **intestinal polypeptide** analogs include peptides having the following amino acid sequences:
- SUMM [0148] Particularly common vasoactive **intestinal polypeptide** analogs known in the art include the following:
- SUMM [0268] In the context of the present invention, the ability of various VIP analogs that exhibit VIP **agonist** activity to cross the pertinent epithelial barrier as a naked peptide is expected. Further, those of skill in the art. . .
- SUMM [0273] Additional pharmacologically active agents may be co-administered along with the primary active agent, i.e., with the VIP or VIP **agonist**. Such additional active agents are also referred to herein as "secondary" active agents. Preferred secondary agents are vasoactive agents, particularly. . .
- SUMM . . . (spermine NONOate or "SPER/NO") and sodium (Z)-1-(N,N-diethylamino)-diazene-1-ium-1,2-diolate (diethylamine NONOate or "DEA/NO") and derivatives thereof). Still other vasoactive agents include vasoactive **intestinal polypeptide** analogs and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .
- SUMM [0292] The primary vasoactive agent--i.e., VIP or an **agonist** thereof--and the additional active agent or agents may be incorporated into a single formulation, or they may be administered separately,. . . simultaneously or sequentially. In a preferred embodiment, an androgenic agent is administered prior to administration of VIP or a VIP **agonist**, i.e., the androgenic agent is administered as a pretreatment. In a particularly preferred embodiment, such a method involves administration of. . . topical (preferably vulvar and/or vaginal) administration, followed by topical (again, preferably vulvar

- and/or vaginal) administration of VIP or a VIP **agonist**.
- SUMM [0316] The patient treated may be a woman suffering from some type of **sexual dysfunction** or disorder, or may possess "normal" sexual desire and/or "normal" sexual responsiveness as those terms are understood defined by clinicians. . . . responsiveness relative to her typical sexual experience. Often, however, the female patient seeking enhanced sexual desire and responsiveness suffers a **sexual dysfunction** such as a condition, disease or disorder that affects one of the four stages of the female sexual response: excitement,
- SUMM kit is provided that contains the pharmaceutical formulation to be administered, i.e., a pharmaceutical formulation containing VIP or a VIP **agonist** for enhancing female sexual desire and responsiveness, a container (e.g., a vial, a bottle, a pouch, an envelope, a can,
- DETD [0349] Individuals are assessed and pre-screened to assemble an experimental group of subjects suffering from **sexual dysfunction**. The compositions prepared in Examples 1-9, formulated with VIP or an analog thereof, are each assessed in the experimental subjects. . . .
- CLM What is claimed is:
1. A method for treating **sexual dysfunction** in a female individual, comprising administering to the vagina and/or vulvar region of the individual a pharmaceutical formulation that comprises a therapeutically effective amount of a vasoactive agent selected from the group consisting vasoactive **intestinal polypeptide** and agonists thereof.
 15. The method of claim 1, wherein the vasoactive agent is vasoactive **intestinal polypeptide**.
 16. The method of claim 1, wherein the vasoactive agent is a vasoactive **intestinal polypeptide agonist**.
 17. The method of claim 16, wherein the vasoactive **intestinal polypeptide agonist** comprises a polypeptide sequence comprising a human vasoactive **intestinal polypeptide** sequence having amino acid substitutions at one or more positions.
 18. The method of claim 17, wherein the vasoactive **intestinal polypeptide agonist** is terminally modified.
 19. The method of claim 16, wherein the vasoactive intestinal peptide **agonist** comprises at least one **agonist** selected from the group consisting of SEQ. ID. NOS.:2-205 inclusive.
 21. The method of claim 20, wherein the androgenic agent is selected from the group consisting of **androsterone**, **androsterone** acetate, **androsterone** propionate, **androsterone** benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, dehydroepiandrosterone, sodium dehydroepiandrosterone sulfate, 4-dihydrotestosterone, dromostanolone, dromostanolone propionate, ethylestrenol, fluoxymesterone, methyltestosterone, nandrolone. . . .
- hours prior to sexual activity, a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide**, agonists thereof, and combinations thereof.

- . . . individual, on an as-needed basis, a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide**, agonists thereof, and combinations thereof.
 - . . . individual, on an as-needed basis, a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide**, agonists thereof, and combinations thereof.
 - . . . female individual suffering from dyspareunia a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide**, agonists thereof, and combinations thereof.
 - . . . in need of such treatment a therapeutically effective amount of a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide**, agonists thereof, and combinations thereof, on an as-needed basis.
 - . . . sexual desire and responsiveness in a female individual, comprising administering a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide**, agonists thereof, and combinations thereof to the individual in an amount effective to provide a blood level of the agent. . .
 - . . . responsiveness, comprising (a) approximately 1.0 .mu.g to 1.0 g of a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide**, agonists thereof, and combinations thereof, per gram of formulation, (b) a pharmaceutically acceptable carrier suitable for vaginal and/or vulvar administration.
35. The formulation of claim 29, wherein the vasoactive agent is vasoactive **intestinal polypeptide**.
36. The formulation of claim 29, wherein the vasoactive agent is a vasoactive **intestinal polypeptide agonist**.
37. The formulation of claim 36, wherein the vasoactive **intestinal polypeptide agonist** comprises a polypeptide sequence comprising a human vasoactive **intestinal polypeptide** sequence having amino acid substitutions at one or more positions.
38. The formulation of claim 37, wherein the vasoactive **intestinal polypeptide agonist** is terminally modified.
39. The formulation of claim 36, wherein the vasoactive intestinal peptide **agonist** comprises at least one **agonist** selected from the group consisting of SEQ. ID. NOS.:2-205 inclusive.
- . . . enhancing sexual desire and responsiveness, comprising: a pharmaceutical formulation of a vasoactive agent selected from the group consisting of vasoactive **intestinal polypeptide** and agonists thereof; a container housing the pharmaceutical formulation during storage and prior to administration; and instructions for carrying out. . .

L5 ANSWER 3 OF 6 USPATFULL

AN 2002:22468 USPATFULL

TI As-needed administration of an androgenic agent to enhance female sexual

desire and responsiveness

IN Wilson, Leland F., Menlo Park, CA, UNITED STATES
 Tam, Peter Y., Redwood City, CA, UNITED STATES

PI US 2002013304 A1 20020131

AI US 2001-919472 A1 20010727 (9)

RLI Continuation-in-part of Ser. No. US 2000-539484, filed on 30 Mar 2000, GRANTED, Pat. No. US 6306841 Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, ABANDONED Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, GRANTED, Pat. No. US 5877216 Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997, ABANDONED

DT Utility

FS APPLICATION

LREP REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO PARK, CA, 94025

CLMN Number of Claims: 62

ECL Exemplary Claim: 1

DRWN No Drawings

LN.CNT 1970

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB A method is provided for enhancing a female individual's sexual desire and responsiveness. The method involves administration of a pharmaceutical formulation containing an effective amount of an androgenic agent, wherein administration is on an as-needed basis rather than involving chronic pharmacotherapy. Local delivery may be accomplished via administration to the vagina, vulvar area or urethra of the individual, although oral administration is preferred for those androgenic agents that are orally active. Formulations and kits for carrying out the method are provided as well.

SUMM . . . and Statistical Manual IV, "Sexual and Gender Identity Disorder," American Psychiatric Association, Washington. D.C., pp.493-539, 1994; Osborn et al. (1988), "**Sexual Dysfunction** Among Middle Aged Women in the Community," British Medical Journal 296:959-962; Frank et al. (1978), "Frequency of **Sexual Dysfunction** in 'Normal Couples'," New England Journal of Medicine, 299:111-115; and Garde et al. (1980), "Female Sexual Behavior: A Study in a Random Sample of Forty-year-old Danish Women," Maturitas 2:225-240). **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York: Brunner-Mazel, 1983), and Kolodny et al., . . .

SUMM [0006] Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health. . .

SUMM [0008] Drug therapy, other than with female hormones, has been described for treating female **sexual dysfunction**. For example, U.S. Pat. No. 4,507,323 to Stern describes the use of the anxiolytic m-chloro-.alpha.-t-butylamino-propiofenone in the treatment of **sexual dysfunction** in both male and female individuals. Pharmaceutical formulations containing the agent are described, which are presented in discrete units, e.g., . . .

SUMM [0009] Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals using the stereoisomers of octahydropyrimido[4,5-

- g]quinolines, centrally acting dopamine agonists.
- SUMM . . . prevention of the occurrence of symptoms and/or their underlying cause, and improvement or remediation of damage. Thus, for example, "treating" **sexual dysfunction**, as the term is used herein, encompasses both prevention of **sexual dysfunction** in clinically asymptomatic individuals and treatment of dysfunction in a clinically symptomatic individual.
- SUMM . . . autonomic neuropathies, diabetes mellitus, and disorders of the innervation of any of the sexual organs. This term also includes substance-induced **sexual dysfunction**, including but not limited to, decreases in desire and responsiveness secondary to anti-depressants, neuroleptics, anti-hypertensives, tobacco, opiates, alcohol and any. . .
- SUMM [0038] the naturally occurring androgens and derivatives thereof, including **androsterone**, **androsterone** acetate, **androsterone** propionate, **androsterone** benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, ethylestrenol, oxandrolone, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate, . . .
- SUMM . . . Preferred secondary agents are vasoactive agents, particularly vasodilators, selected from the group consisting of vasoactive prostaglandins, endothelin-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives, prodrugs, active metabolites, and inclusion complexes thereof, and. . .
- SUMM . . . (spermine NONOate or "SPER/NO") and sodium (Z)-1-(N,N-diethylamino)-diazene-1-ium-1,2-diolate (diethylamine NONOate or "DEA/NO") and derivatives thereof). Still other vasoactive agents include vasoactive **intestinal polypeptide** analogs and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .
- SUMM [0121] The patient treated may be a woman suffering from some type of **sexual dysfunction** or disorder, or may possess "normal" sexual desire and/or "normal" sexual responsiveness as those terms are understood defined by clinicians. . . responsiveness relative to her typical sexual experience. Often, however, the female patient seeking enhanced sexual desire and responsiveness suffers a **sexual dysfunction** such as a condition, disease or disorder that affects one of the four stages of the female sexual response: excitement, . . .
- CLM What is claimed is:
12. The method of claim 2 wherein the androgenic agent is selected from the group consisting of **androsterone**, androstenediol, androstenedione, ethylestrenol, oxandrolone, nandrolone, stanozolol, dromostanolone, testosterone, dehydroepiandrosterone, 4-dihydrotestosterone, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, pharmacologically active salts and esters. . .
- . . . method of claim 36, wherein the vasodilator is selected from the group consisting of vasoactive prostaglandins, endothelin-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and pharmacologically active salts, esters, prodrugs, and metabolites thereof, and combinations of any of. . .
47. The method of claim 46, wherein the additional active agent is a dopamine **agonist**.

48. The method of claim 47, wherein the dopamine **agonist** is selected from the group consisting of levodopa, bromocriptine, pergolide, apomorphine, piribedil, pramipexole, ropinirole, and combinations thereof.

56. The formulation of claim 58 wherein the androgenic agent is selected from the group consisting of **androsterone**, androstenediol, androstenedione, ethylestrenol, oxandrolone, nandrolone phenpropionate, nandrolone, stanozolol, dromostanolone, testosterone, dehydroepiandrosterone, 4-dihydrotestosterone, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, pharmacologically active salts. . .

L5 ANSWER 4 OF 6 USPATFULL
 AN 2001:229703 USPATFULL
 TI Co-administration of a prostaglandin and an androgenic agent in the treatment of female **sexual dysfunction**
 IN Place, Virgil A., Kawaihae, HI, United States
 Wilson, Leland F., Menlo Park, CA, United States
 Doherty, Paul C., JR., Cupertino, CA, United States
 Hanamoto, Mark S., Belmont, CA, United States
 Spivack, Alfred P., Menlo Park, CA, United States
 Gesundheit, Neil, Los Altos, CA, United States
 Bennett, Sean R., Denver, CO, United States
 PI US 2001051656 A1 20011213
 AI US 2001-905458 A1 20010713 (9)
 RLI Continuation of Ser. No. US 2000-539484, filed on 30 Mar 2000, PENDING
 Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, ABANDONED
 Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, GRANTED, Pat. No. US 5877216 Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997, ABANDONED
 DT Utility
 FS APPLICATION
 LREP REED & ASSOCIATES, 800 MENLO AVENUE, SUITE 210, MENLO PARK, CA, 94025
 CLMN Number of Claims: 59
 ECL Exemplary Claim: 1
 DRWN 1 Drawing Page(s)
 LN.CNT 1333
 CAS INDEXING IS AVAILABLE FOR THIS PATENT.
 AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar area or urethra of the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists smooth muscle relaxants leukotriene inhibitors, and other. The formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.
 TI Co-administration of a prostaglandin and an androgenic agent in the treatment of female **sexual dysfunction**
 AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar. . . the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives,

endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists smooth muscle relaxants leukotriene inhibitors, and other. The formulations are also useful for preventing the occurrence of yeast infections, . . .

SUMM [0002] This invention relates generally to methods and pharmaceutical formulations for treating female **sexual dysfunction**, and more particularly relates to vaginal, vulvar and/or urethral administration of a vasoactive agent, such as a prostaglandin, in such.

SUMM . . . vaginal surface lubrication as a result of plasma transudation that saturates the fluid reabsorptive capacity of the vaginal epithelium. Vasoactive **intestinal polypeptide** ("VIP") release may induce the physiological changes of sexual arousal and excitement, and may be the major neurotransmitter that participates.

SUMM . . . characteristic genital and extragenital responses occur. Estrogens magnify the sexual responses; however, sexual responses may also occur in estrogen-deficient individuals. **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York: Brunner-Mazel, 1983), and Kolodny et al., . . .

SUMM [0007] Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health. . .

SUMM . . . of menstrual periods. Accordingly, there remains a need in the art to provide safer and more ways of treating female **sexual dysfunction**.

SUMM . . . present invention is directed to the aforementioned need in the art, and provides a new, highly effective method of treating **sexual dysfunction** in women. The method involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, e.g., a . . .

SUMM [0010] Drug therapy for treating female **sexual dysfunction** has been described. For example, U.S. Pat. No. 4,507,323 to Stern describes the use of the anxiolytic m-chloro-.alpha.-t-butylamino-propiofenone in the treatment of **sexual dysfunction** in both male and female individuals. Pharmaceutical compositions containing the agent are described, which are presented in discrete units, e.g., . . .

SUMM [0011] Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals using the stereoisomers of octahydropyrimido[4,5-quinolines, centrally acting dopamine **agonist**.

SUMM . . . are mentioned as being suitable for use in conjunction with the device. However, the patent does not mention treatment of **sexual dysfunction**, nor is application of a drug-containing composition to the clitoris, vulvar area or urethra disclosed or suggested. U.S. Pat. No. . . .

SUMM . . . mention that delivery of prostaglandins is a preferred use of the invention; however, there is no disclosure concerning treatment of **sexual dysfunction** or delivery to the vulvar area or urethra.

SUMM . . . drug delivery, urethral drug administration, application of a drug-containing formulation to the clitoris or surrounding vulvar area, or treatment of **sexual dysfunction**.

SUMM . . . patents focus on the use of prostaglandins in contraceptives, labor and delivery, and do not pertain to treatment of female **sexual dysfunction**.

SUMM [0025] Several references are also of interest herein insofar as they pertain to urethral drug administration to treat **sexual dysfunction** in men, e.g., vasculogenic impotence or the like. See, for example, U.S. Pat. Nos. 5,242,391, 5,474,535, 5,686,093 and 5,773,020 to. . .

SUMM [0026] There are, accordingly, a number of background references relating to treatment of female **sexual dysfunction**, cervical or uterine administration of prostaglandins, and urethral drug administration in men. However, the present method for treating female **sexual dysfunction**, by way of vaginal, vulvar and/or urethral delivery of a vasoactive agent such as a prostaglandin, is completely novel and. . .

SUMM [0027] Accordingly, it is a primary object of the invention to provide a method for treating **sexual dysfunction** in a female individual by administering a pharmaceutical formulation containing a selected vasoactive agent to the vagina, vulvar area or. . .

SUMM [0032] In one aspect of the invention, then, a method is provided for treating **sexual dysfunction** in a female individual comprising administering to the vagina, vulvar area or urethra a pharmaceutical formulation containing a selected vasoactive. . . vasodilator, with preferred vasodilators selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide agonist**, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives and inclusion complexes thereof, and combinations of any of. . .

DETD . . . meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect. For example, in treating **sexual dysfunction** in women, an "effective" amount of drug would be an amount that is at least sufficient to provide the desired. . .

DETD [0047] In a first embodiment, the invention relates to a method for treating **sexual dysfunction** in a female individual and involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, preferably. . . vasodilator. Preferred vasodilators are selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide agonists**, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives, prodrugs, and inclusion complexes thereof, and combinations of. . .

DETD . . . (spermine NONOate or "SPER/NO") and sodium (Z)-1-(N,N-diethylamino)-diazen-1-ium-1,2-diolate (diethylamine NONOate or "DEA/NO") and derivatives thereof). Still other vasoactive agents include vasoactive **intestinal polypeptide agonists** and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .

DETD . . . more pharmacologically active agents other than the vasoactive agent. For example, the formulations may contain a steroid or a steroid **agonist**, partial **agonist**, or antagonist.

DETD . . . in the formulation. Suitable androgenic agents include, but are not limited to: the naturally occurring androgens and derivatives

thereof, including **androsterone**, **androsterone** acetate, **androsterone** propionate, **androsterone** benzoate, **androstenediol**, **androstenediol-3-acetate**, **androstenediol-17-acetate**, **androstenediol-3,17-diacetate**, **androstenediol-17-benzoate**, **androstenediol-3-acetate-17-benzoate**, **androstenedione**, **ethylestrenol**, **oxandrolone**, **nandrolone phenpropionate**, **nandrolone decanoate**, **nandrolone furylpropionate**, **nandrolone cyclohexane-propionate**, **nandrolone benzoate**,. . . .

DETD [0086] For treatment of **sexual dysfunction**, the pharmaceutical formulation is administered either vaginally, to the vulvar area, and/or to the urethra The amount of active agent. . . .

DETD [0087] In addition to treatment of **sexual dysfunction**, the formulations of the invention have other uses as well. They may be administered vaginally to prevent the occurrence of. . . .

DETD [0108] Individuals are assessed and pre-screened to assemble an experimental group of subjects suffering from **sexual dysfunction**. The compositions prepared in Examples 1-6, formulated with prostaglandin E.sub.1, each assessed in the experimental subjects for their ability to. . . .

CLM What is claimed is:

1. A method for treating **sexual dysfunction** in a female individual, comprising administering to the vagina, vulvar area or urethra of the individual a pharmaceutical formulation that. . . . of a vasoactive agent selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, calcium channel blockers, phosphodiesterase inhibitors, nitrates, .alpha.-receptor blocking agents, ergotamine drugs, antihypertensive agents, pharmacologically. . . .
13. The method of claim 1, wherein the vasodilating agent is a vasoactive **intestinal polypeptide** agonist.

44. A method for preventing the occurrence of a yeast infection in a female individual, comprising vaginally administering to such. . . . comprises a vasoactive agent selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, calcium channel blockers, phosphodiesterase inhibitors, nitrates, .alpha.-receptor blocking agents, ergotamine drugs, antihypertensive agents, pharmaceutically. . . .

. . . comprises a vasoactive agent selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, calcium channel blockers, phosphodiesterase inhibitors, nitrates, .alpha.-receptor blocking agents, ergotamine drugs, antihypertensive agents, pharmaceutically. . . .

. . . comprises a vasoactive agent selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, calcium channel phosphodiesterase blockers, phosphodiesterase inhibitors, nitrates, .alpha.-receptor blocking agents, ergotamine drugs, antihypertensive agents,. . . .

. . . comprises a vasoactive agent selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene

inhibitors, calcium channel blockers, phosphodiesterase inhibitors, nitrates, .alpha.-receptor blocking agents, ergotamine drugs, antihypertensive agents, pharmaceutically. . . .

48. A pharmaceutical formulation for treating **sexual dysfunction** in a female individual, comprising an amount of a vasoactive agent effective to treat female **sexual dysfunction**, wherein the vasoactive agent is selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, calcium channel blockers, phosphodiesterase inhibitors, nitrates, .alpha.-receptor blocking agents, ergotamine drugs, antihypertensive agents, pharmaceutically. . . .

56. The device of claim 55, wherein the pharmaceutical formulation is effective to treat **sexual dysfunction** in a female individual, and comprises an effective amount of a vasoactive agent.

L5 ANSWER 5 OF 6 USPATFULL
 AN 2001:185276 USPATFULL
 TI Treatment of female **sexual dysfunction**
 IN Place, Virgil A., Kawaihae, HI, United States
 Wilson, Leland F., Menlo Park, CA, United States
 Doherty, Jr., Paul C., Cupertino, CA, United States
 Hanamoto, Mark S., Belmont, CA, United States
 Spivack, Alfred P., Menlo Park, CA, United States
 Gesundheit, Neil, Los Altos, CA, United States
 Bennett, Sean R., Denver, CO, United States
 PA ASIVI, LLC, Mountain View, CA, United States (U.S. corporation)
 PI US 6306841 B1 20011023
 AI US 2000-539484 20000330 (9)
 RLI Continuation of Ser. No. US 1998-181316, filed on 27 Oct 1998, now abandoned Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, now patented, Pat. No. US 5877216 Continuation of Ser. No. US 1997-959057, filed on 28 Oct 1997, now abandoned
 DT Utility
 FS GRANTED
 EXNAM Primary Examiner: Criares, Theodore J.
 LREP Reed, Dianne E. Reed & Associates
 CLMN Number of Claims: 31
 ECL Exemplary Claim: 1
 DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
 LN.CNT 1196
 CAS INDEXING IS AVAILABLE FOR THIS PATENT.
 AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar area or urethra of the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and others. The formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.
 TI Treatment of female **sexual dysfunction**
 AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered

to the vagina, vulvar. . . the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and others. The formulations are also useful for preventing the occurrence of yeast infections, . . .

SUMM This invention relates generally to methods and pharmaceutical formulations for treating female **sexual dysfunction**, and more particularly relates to vaginal, vulvar and/or urethral administration of a vasoactive agent, such as a prostaglandin, in such.

SUMM . . . vaginal surface lubrication as a result of plasma transudation that saturates the fluid reabsorptive capacity of the vaginal epithelium. Vasoactive **intestinal polypeptide** ("VIP") release may induce the physiological changes of sexual arousal and excitement, and may be the major neurotransmitter that participates.

SUMM . . . characteristic genital and extragenital responses occur. Estrogens magnify the sexual responses; however, sexual responses may also occur in estrogen-deficient individuals. **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York: Brunner-Mazel, 1983), and Kolodny et al., . . .

SUMM Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health. . .

SUMM . . . of menstrual periods. Accordingly, there remains a need in the art to provide safer and more ways of treating female **sexual dysfunction**.

SUMM . . . present invention is directed to the aforementioned need in the art, and provides a new, highly effective method of treating **sexual dysfunction** in women. The method involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, e.g., a. . .

SUMM Drug therapy for treating female **sexual dysfunction** has been described. For example, U.S. Pat. No. 4,507,323 to Stem describes the use of the anxiolytic m-chloro-.alpha.-t-butylaminopropiophenone in the treatment of **sexual dysfunction** in both male and female individuals. Pharmaceutical compositions containing the agent are described, which are presented in discrete units, e.g., . . .

SUMM Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals using the stereoisomers of octahydropyrimido[4,5-g]quinolines, centrally acting dopamine agonists.

SUMM . . . are mentioned as being suitable for use in conjunction with the device. However, the patent does not mention treatment of **sexual dysfunction**, nor is application of a drug-containing composition to the clitoris, vulvar area or urethra disclosed or suggested. U.S. Pat. No. . . .

SUMM . . . mention that delivery of prostaglandins is a preferred use of the invention; however, there is no disclosure concerning treatment of

- sexual dysfunction** or delivery to the vulvar area or urethra.
- SUMM . . . drug delivery, urethral drug administration, application of a drug-containing formulation to the clitoris or surrounding vulvar area, or treatment of **sexual dysfunction**.
- SUMM . . . patents focus on the use of prostaglandins in contraceptives, labor and delivery, and do not pertain to treatment of female **sexual dysfunction**.
- SUMM Several references are also of interest herein insofar as they pertain to urethral drug administration to treat **sexual dysfunction** in men, e.g., vasculogenic impotence or the like. See, for example, U.S. Pat. Nos. 5,242,391, 5,474,535, 5,686,093 and 5,773,020 to. . .
- SUMM There are, accordingly, a number of background references relating to treatment of female **sexual dysfunction**, cervical or uterine administration of prostaglandins, and urethral drug administration in men. However, the present method for treating female **sexual dysfunction**, by way of vaginal, vulvar and/or urethral delivery of a vasoactive agent such as a prostaglandin, is completely novel and. . .
- SUMM Accordingly, it is a primary object of the invention to provide a method for treating **sexual dysfunction** in a female individual by administering a pharmaceutical formulation containing a selected vasoactive agent to the vagina, vulvar area or. . .
- SUMM In one aspect of the invention, then, a method is provided for treating **sexual dysfunction** in a female individual comprising administering to the vagina, vulvar area or urethra a pharmaceutical formulation containing a selected vasoactive. . . vasodilator, with preferred vasodilators selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives and inclusion complexes thereof, and combinations of any. . .
- DETD . . . meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect. For example, in treating **sexual dysfunction** in women, an "effective" amount of drug would be an amount that is at least sufficient to provide the desired. . .
- DETD In a first embodiment, the invention relates to a method for treating **sexual dysfunction** in a female individual and involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, preferably. . . vasodilator. Preferred vasodilators are selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives, prodrugs, and inclusion complexes thereof, and combinations of. . .
- DETD . . . (spermine NONOate or "SPER/NO") and sodium (Z)-1-(N,N-diethylamino)-diazene-1-ium-1,2-diolate (diethylamine NONOate or "DEA/NO") and derivatives thereof). Still other vasoactive agents include vasoactive **intestinal polypeptide** agonists and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .
- DETD . . . more pharmacologically active agents other than the vasoactive agent. For example, the formulations may contain a steroid or a steroid **agonist**, partial **agonist**, or antagonist.

DETD . . . in the formulation. Suitable androgenic agents include, but are not limited to: the naturally occurring androgens and derivatives thereof, including **androsterone**, **androsterone** acetate, **androsterone** propionate, **androsterone** benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, ethylestrenol, oxandrolone, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexanepropionate, nandrolone benzoate, .

DETD For treatment of **sexual dysfunction**, the pharmaceutical formulation is administered either vaginally, to the vulvar area, and/or to the urethra. The amount of active agent. . .

DETD In addition to treatment of **sexual dysfunction**, the formulations of the invention have other uses as well. They may be administered vaginally to prevent the occurrence of. . .

DETD Individuals are assessed and pre-screened to assemble an experimental group of subjects suffering from **sexual dysfunction**. The compositions prepared in Examples 1-6, formulated with prostaglandin E.sub.1, each assessed in the experimental subjects for their ability to. . .

CLM What is claimed is:
1. A method for treating **sexual dysfunction** in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that. . .

L5 ANSWER 6 OF 6 USPATFULL

AN 2001:163217 USPATFULL

TI Treatment of female **sexual dysfunction**

IN Place, Virgil A., Kawaihee, HI, United States
Wilson, Leland F., Menlo Park, CA, United States
Doherty, Jr., Paul C., Cupertino, CA, United States
Hanamoto, Mark S., Belmont, CA, United States
Spivack, Alfred P., Menlo Park, CA, United States
Gesundheit, Neil, Los Altos, CA, United States
Bennett, Sean R., Denver, CO, United States

PA Asivi, LLC, Mountain View, CA, United States (U.S. corporation)

PI US 6294550 B1 20010925

AI US 2000-501098 20000209 (9)

RLI Division of Ser. No. US 1998-181316, filed on 27 Oct 1998
Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997, now patented, Pat. No. US 5877216 Continuation-in-part of Ser. No. US 1997-959057, filed on 28 Oct 1997, now abandoned

DT Utility

FS GRANTED

EXNAM Primary Examiner: Criares, Theodore J.

LREP Reed, Dianne E. Reed & Associates

CLMN Number of Claims: 29

ECL Exemplary Claim: 1

DRWN 2 Drawing Figure(s); 1 Drawing Page(s)

LN.CNT 1195

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar area or urethra of the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal**

polypeptide agonists, smooth muscle relaxants, leukotriene inhibitors, and others. The formulations are also useful for preventing the occurrence of yeast infections, improving vaginal muscle tone and tissue health, enhancing vaginal lubrication, and minimizing excess collagen deposition. A clitoral drug delivery device is also provided.

TI Treatment of female **sexual dysfunction**

AB Methods and formulations for treating female **sexual dysfunction** are provided. A pharmaceutical composition formulated so as to contain a selected vasoactive agent is administered to the vagina, vulvar. . . the individual undergoing treatment. Suitable vasoactive agents are vasodilators, including naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and others. The formulations are also useful for preventing the occurrence of yeast infections, . . .

SUMM This invention relates generally to methods and pharmaceutical formulations for treating female **sexual dysfunction**, and more particularly relates to vaginal, vulvar and/or urethral administration of a vasoactive agent, such as a prostaglandin, in such.

SUMM . . . vaginal surface lubrication as a result of plasma transudation that saturates the fluid reabsorptive capacity of the vaginal epithelium. Vasoactive **intestinal polypeptide** ("VIP") release may induce the physiological changes of sexual arousal and excitement, and may be the major neurotransmitter that participates.

SUMM . . . characteristic genital and extragenital responses occur. Estrogens magnify the sexual responses; however, sexual responses may also occur in estrogen-deficient individuals. **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York: Brunner-Mazel, 1983), and Kolodny et al., . . .

SUMM Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health. . .

SUMM . . . of menstrual periods. Accordingly, there remains a need in the art to provide safer and more ways of treating female **sexual dysfunction**.

SUMM . . . present invention is directed to the aforementioned need in the art, and provides a new, highly effective method of treating **sexual dysfunction** in women. The method involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, e.g., a. . .

SUMM Drug therapy for treating female **sexual dysfunction** has been described. For example, U.S. Pat. No. 4,507,323 to Stern describes the use of the anxiolytic m-chloro-.alpha.-t-butylamino-propiofenone in the treatment of **sexual dysfunction** in both male and female individuals. Pharmaceutical compositions containing the agent are described, which are presented in discrete units, e.g., . . .

SUMM Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals

using the stereoisomers of octahydropyrimido[4,5-g]quinolines, centrally acting dopamine agonists.

SUMM . . . are mentioned as being suitable for use in conjunction with the device. However, the patent does not mention treatment of **sexual dysfunction**, nor is application of a drug-containing composition to the clitoris, vulvar area or urethra disclosed or suggested. U.S. Pat. No. . . .

SUMM . . . mention that delivery of prostaglandins is a preferred use of the invention; however, there is no disclosure concerning treatment of **sexual dysfunction** or delivery to the vulvar area or urethra.

SUMM . . . drug delivery, urethral drug administration, application of a drug-containing formulation to the clitoris or surrounding vulvar area, or treatment of **sexual dysfunction**.

SUMM . . . patents focus on the use of prostaglandins in contraceptives, labor and delivery, and do not pertain to treatment of female **sexual dysfunction**.

SUMM Several references are also of interest herein insofar as they pertain to urethral drug administration to treat **sexual dysfunction** in men, e.g., vasculogenic impotence or the like. See, for example, U.S. Pat. Nos. 5,242,391, 5,474,535, 5,686,093 and 5,773,020 to. . .

SUMM There are, accordingly, a number of background references relating to treatment of female **sexual dysfunction**, cervical or uterine administration of prostaglandins, and urethral drug administration in men. However, the present method for treating female **sexual dysfunction**, by way of vaginal, vulvar and/or urethral delivery of a vasoactive agent such as a prostaglandin, is completely novel and. . .

SUMM Accordingly, it is a primary object of the invention to provide a method for treating **sexual dysfunction** in a female individual by administering a pharmaceutical formulation containing a selected vasoactive agent to the vagina, vulvar area or. . .

SUMM In one aspect of the invention, then, a method is provided for treating **sexual dysfunction** in a female individual comprising administering to the vagina, vulvar area or urethra a pharmaceutical formulation containing a selected vasoactive. . . vasodilator, with preferred vasodilators selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives and inclusion complexes thereof, and combinations of any. . .

DETD . . . meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect. For example, in treating **sexual dysfunction** in women, an "effective" amount of drug would be an amount that is at least sufficient to provide the desired. . .

DETD In a first embodiment, the invention relates to a method for treating **sexual dysfunction** in a female individual and involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, preferably. . . vasodilator. Preferred vasodilators are selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives, prodrugs, and inclusion complexes thereof, and combinations of. . .

DETD . . . (spermine NONOate or "SPER/NO") and sodium (Z)-1-(N,N-

diethylamino)-diazene-1-ium-1,2-diolate (diethylamine NONOate or "DEA/NO") and derivatives thereof). Still other vasoactive agents include vasoactive **intestinal polypeptide** agonists and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .

DETD . . . more pharmacologically active agents other than the vasoactive agent. For example, the formulations may contain a steroid or a steroid **agonist**, partial **agonist**, or antagonist.

DETD . . . in the formulation. Suitable androgenic agents include, but are not limited to: the naturally occurring androgens and derivatives thereof, including **androsterone**, **androsterone** acetate, **androsterone** propionate, **androsterone** benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, ethylestrenol, oxandrolone, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexane-propionate, nandrolone benzoate,. . .

DETD For treatment of **sexual dysfunction**, the pharmaceutical formulation is administered either vaginally, to the vulvar area, and/or to the urethra. The amount of active agent. . .

DETD In addition to treatment of **sexual dysfunction**, the formulations of the invention have other uses as well. They may be administered vaginally to prevent the occurrence of. . .

DETD Individuals are assessed and pre-screened to assemble an experimental group of subjects suffering from **sexual dysfunction**. The compositions prepared in Examples 1-6, formulated with prostaglandin E.sub.1, each assessed in the experimental subjects for their ability to. . .

CLM What is claimed is:
1. A method for treating **sexual dysfunction** in a female individual, comprising administering to the vagina, vulvar area and/or urethra of the individual a pharmaceutical formulation that. . .

=> s 12 and vagina

5486 VAGINA

L6 13 L2 AND VAGINA

=> d his

(FILE 'HOME' ENTERED AT 10:43:53 ON 28 OCT 2002)

FILE 'USPATFULL' ENTERED AT 10:44:01 ON 28 OCT 2002

L1 309 S INTESTINAL POLYPEPTIDE
L2 36 S L1 AND SEXUAL DYSFUNCTION?
L3 18 S L2 AND AGONIST
L4 3 S L3 AND PD<2000
L5 6 S L3 AND ANDROSTERONE
L6 13 S L2 AND VAGINA

=> d 16 and 12

L2 IS NOT VALID HERE

For an explanation, enter "HELP DISPLAY".

=> s 12 and 16

L7 13 L2 AND L6

=> d 17 bib, ab, kwic

L7 ANSWER 1 OF 13 USPATFULL
 AN 2002:276096 USPATFULL
 TI Treatment of female **sexual dysfunction** using
 phosphodiesterase inhibitors
 IN Place, Virgil A., Kawaihae, HI, United States
 Wilson, Leland F., Menlo Park, CA, United States
 Doherty, Jr., Paul C., Cupertino, CA, United States
 Hanamoto, Mark S., Belmont, CA, United States
 Spivack, Alfred P., Menlo Park, CA, United States
 Gesundheit, Neil, Los Altos, CA, United States
 Bennett, Sean R., Denver, CO, United States
 PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)
 PI US 6469016 B1 20021022
 AI US 2000-499959 20000208 (9)
 RLI Division of Ser. No. US 1998-181316, filed on 27 Oct 1998, now abandoned
 Continuation-in-part of Ser. No. US 1997-959064, filed on 28 Oct 1997,
 now patented, Pat. No. US 5877216 Continuation-in-part of Ser. No. US
 1997-959057, filed on 28 Oct 1997, now abandoned
 DT Utility
 FS GRANTED
 EXNAM Primary Examiner: Criares, Theodore J.
 LREP Reed & Associates, Reed, Diane E.
 CLMN Number of Claims: 64
 ECL Exemplary Claim: 1
 DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
 LN.CNT 1559
 AB Methods and formulations for treating female **sexual
 dysfunction** are provided. A pharmaceutical composition
 formulated so as to contain a selected vasoactive agent is administered
 to the **vagina**, vulvar area or urethra of the individual
 undergoing treatment. Suitable vasoactive agents are vasodilators,
 including naturally occurring prostaglandins, synthetic prostaglandin
 derivatives, endothelial-derived relaxation factors, vasoactive
intestinal polypeptide agonists, smooth muscle
 relaxants, leukotriene inhibitors, and others. The formulations are also
 useful for preventing the occurrence of yeast infections, improving
 vaginal muscle tone and tissue health, enhancing vaginal lubrication,
 and minimizing excess collagen deposition. A clitoral drug delivery
 device is also provided.
 TI Treatment of female **sexual dysfunction** using
 phosphodiesterase inhibitors
 AB Methods and formulations for treating female **sexual
 dysfunction** are provided. A pharmaceutical composition
 formulated so as to contain a selected vasoactive agent is administered
 to the **vagina**, vulvar area or urethra of the individual
 undergoing treatment. Suitable vasoactive agents are vasodilators,
 including naturally occurring prostaglandins, synthetic prostaglandin
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intestinal polypeptide agonists, smooth muscle
 relaxants, leukotriene inhibitors, and others. The formulations are also
 useful for preventing the occurrence of yeast infections,. . .
 SUMM This invention relates generally to methods and pharmaceutical
 formulations for treating female **sexual dysfunction**,
 and more particularly relates to vaginal, vulvar and/or urethral
 administration of a vasoactive agent, such as a prostaglandin, in such.
 SUMM . . . vaginal surface lubrication as a result of plasma transudation
 that saturates the fluid reabsorptive capacity of the vaginal

epithelium. Vasoactive **intestinal polypeptide** ("VIP") release may induce the physiological changes of sexual arousal and excitement, and may be the major neurotransmitter that participates.

- SUMM . . . characteristic genital and extragenital responses occur. Estrogens magnify the sexual responses; however, sexual responses may also occur in estrogen-deficient individuals. **Sexual dysfunction** may be due to organic or functional disturbances. For example, a variety of diseases affecting neurologic function, including diabetes mellitus. . . also affect a woman's sexual response. In addition, estrogen deficiency, causing vaginal atrophy and dyspareunia, is a common cause of **sexual dysfunction**. For a discussion of other causes of female **sexual dysfunction**, see, e.g., Kaplan, The Evaluation of Sexual Disorders: Psychological and Medical Aspects (New York: Brunner-Mazel, 1983), and Kolodny et al., . . .
- SUMM Estrogen therapy is commonly used in the pharmacological treatment of **sexual dysfunction** in women. Estrogen-based therapies are generally used to increase mucous production, provide vasodilatory effects, or to increase the general health of the **vagina**. Nadelson et al., eds., Treatment Interventions in Human Sexuality (New York: Plenum Press, 1983). In such treatments, estrogen is administered.
- SUMM . . . of menstrual periods. Accordingly, there remains a need in the art to provide safer and more ways of treating female **sexual dysfunction**.
- SUMM . . . present invention is directed to the aforementioned need in the art, and provides a new, highly effective method of treating **sexual dysfunction** in women. The method involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, e.g., a . . .
- SUMM Drug therapy for treating female **sexual dysfunction** has been described. For example, U.S. Pat. No. 4,507,323 to Stern describes the use of the anxiolytic m-chloro-.alpha.-t-butylamino-propiofenone in the treatment of **sexual dysfunction** in both male and female individuals. Pharmaceutical compositions containing the agent are described, which are presented in discrete units, e.g., . . .
- SUMM Additionally, U.S. Pat. No. 4,521,421 to Foreman describes the treatment of **sexual dysfunction** in male and female individuals using the stereoisomers of octahydropyrimido[4,5-g]quinolines, centrally acting dopamine agonists.
- SUMM . . . are mentioned as being suitable for use in conjunction with the device. However, the patent does not mention treatment of **sexual dysfunction**, nor is application of a drug-containing composition to the clitoris, vulvar area or urethra disclosed or suggested. U.S. Pat. No. . . .
- SUMM . . . Pat. No. 4,014,987 to Heller et al. describes a tampon-like device for delivery of a drug to the uterus or **vagina**. Heller et al. mention that delivery of prostaglandins is a preferred use of the invention; however, there is no disclosure concerning treatment of **sexual dysfunction** or delivery to the vulvar area or urethra.
- SUMM . . . drug delivery, urethral drug administration, application of a drug-containing formulation to the clitoris or surrounding vulvar area, or treatment of **sexual dysfunction**.
- SUMM . . . patents focus on the use of prostaglandins in contraceptives, labor and delivery, and do not pertain to treatment of female **sexual dysfunction**.
- SUMM Several references are also of interest herein insofar as they pertain

to urethral drug administration to treat **sexual dysfunction** in men, e.g., vasculogenic impotence or the like. See, for example, U.S. Pat. Nos. 5,242,391, 5,474,535, 5,686,093 and 5,773,020 to. . .

SUMM There are, accordingly, a number of background references relating to treatment of female **sexual dysfunction**, cervical or uterine administration of prostaglandins, and urethral drug administration in men. However, the present method for treating female **sexual dysfunction**, by way of vaginal, vulvar and/or urethral delivery of a vasoactive agent such as a prostaglandin, is completely novel and. . .

SUMM Accordingly, it is a primary object of the invention to provide a method for treating **sexual dysfunction** in a female individual by administering a pharmaceutical formulation containing a selected vasoactive agent to the **vagina**, vulvar area or urethra of the individual undergoing treatment.

SUMM In one aspect of the invention, then, a method is provided for treating **sexual dysfunction** in a female individual comprising administering to the **vagina**, vulvar area or urethra a pharmaceutical formulation containing a selected vasoactive agent. The vasoactive agent is preferably a vasodilator, with preferred vasodilators selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives and inclusion complexes thereof, and combinations of any. . .

DETD The term "vaginal delivery" is used herein to mean direct administration of a pharmaceutical composition to the **vagina** of the individual undergoing treatment. Generally, "vaginal delivery" of a pharmaceutical composition involves administration to the distal several centimeters of the **vagina**.

DETD . . . meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect. For example, in treating **sexual dysfunction** in women, an "effective" amount of drug would be an amount that is at least sufficient to provide the desired. . .

DETD In a first embodiment, the invention relates to a method for treating **sexual dysfunction** in a female individual and involves vaginal, vulvar and/or urethral administration of a pharmaceutical formulation containing a vasoactive agent, preferably. . . vasodilator. Preferred vasodilators are selected from the group consisting of naturally occurring prostaglandins, synthetic prostaglandin derivatives, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, pharmaceutically acceptable salts, esters, analogs, derivatives, prodrugs, and inclusion complexes thereof, and combinations of. . .

DETD . . . (spermine NONOate or "SPER/NO") and sodium (Z)-1-(N,N-diethylamino)-diazen-1-ium-1,2-diolate (diethylamine NONOate or "DEA/NO") and derivatives thereof). Still other vasoactive agents include vasoactive **intestinal polypeptide** agonists and derivatives thereof (particularly derivatives in the form of hydrolyzable lower alkyl esters), smooth muscle relaxants, leukotriene inhibitors, calcium. . .

DETD . . . formulations used in the present methods include an enzyme inhibitor, i.e., a compound effective to inhibit enzymes present in the **vagina**, vulvar area or urethra that could degrade or metabolize the pharmacologically active agent. For example, with a prostaglandin as the. . .

DETD . . . has dissolved, the agent core is available for immediate

release and adsorption across the epithelial or mucosal surfaces of the **vagina** or vulvar area. Bioerodible coating materials may be selected from a variety of natural and synthetic polymers, depending on the. . .

DETD . . . of, for example, an erodible wax. The agent is released for adsorption across the epithelial or mucosal surfaces of the **vagina** or vulvar area as the matrix bioerodes. The rate of agent availability is generally controlled by the rate of penetration. . .

DETD For treatment of **sexual dysfunction**, the pharmaceutical formulation is administered either vaginally, to the vulvar area, and/or to the urethra The amount of active agent. . .

DETD In addition to treatment of **sexual dysfunction**, the formulations of the invention have other uses as well. They may be administered vaginally to prevent the occurrence of. . .

DETD Individuals are assessed and pre-screened to assemble an experimental group of subjects suffering from **sexual dysfunction**. The compositions prepared in Examples 1-6, formulated with prostaglandin E.sub.1, each assessed in the experimental subjects for their ability to. . . photoplethysmography (Levin (1980) Clinics in Obstet. Gynaecol. 7:213-252), heated oxygen electrode (Wagner et al. (1978), "Vaginal Fluid" in The Human **Vagina**, Evans et al. (eds.), Amsterdam: Elsevier/North Holland Biomedical Press, pp. 121-137), and direct clearance of radioactive Xenon (Wagner et al.. . .

DETD Decreased vaginal dryness and/or dyspareunia are negatively correlated with vaginal blood flow rates, wherein increased blood flow to the **vagina** correlates with increased lubrication and decreased frequency and severity of dyspareunia (Sarrel, P. M. (1990) Obstet. Gynaecol. 75: 26S-32S). Accordingly,. . . 248:445-448. The compositions of Examples 1-6, when assessed using such methods, are found to substantially increase blood flow to the **vagina** and vulvar area and alleviate vaginal dryness.

CLM What is claimed is:

1. A method for treating **sexual dysfunction** in a female individual, comprising administering to the **vagina** and/or vulvar area of the individual a pharmaceutical formulation that comprises an effective amount of a vasoactive agent selected from. . .
14. The method of claim 1, wherein the **sexual dysfunction** is an excitement stage dysfunction.

15. The method of claim 14, wherein the **sexual dysfunction** involves touch sensation impairment, loss of clitoral sensation, dyspareunia, or a combination thereof.

16. The method of claim 1, wherein the **sexual dysfunction** involves dyspareunia.

36. A method for treating **sexual dysfunction** in a female individual, comprising administering to the **vagina** and/or vulvar area of the individual (a) a therapeutically effective amount of a Type V phosphodiesterase inhibitor or a pharmaceutically. . .

. . . method of claim 37, wherein the additional vasodilator is selected from the group consisting of prostaglandins, endothelial-derived relaxation factors, vasoactive **intestinal polypeptide** agonists, smooth muscle relaxants, leukotriene inhibitors, and combinations thereof.

53. The method of claim 36, wherein the **sexual dysfunction** is an excitement stage dysfunction.

54. The method of claim 53, wherein the **sexual dysfunction** involves touch sensation impairment, loss of clitoral sensation, dyspareunia, or a combination thereof.

55. The method of claim 36, wherein the **sexual dysfunction** involves dyspareunia.